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EN 60601-2-24

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English Version

Medical electrical equipment - Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers (IEC 60601-2-24:2012)

Appareils électromédicaux - Partie 2-24: Exigences particulières pour la sécurité de base et les performances essentielles des pompes et régulateurs de perfusion (IEC 60601-2-24:2012)

Medizinische elektrische Geräte - Teil 2-24: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Infusionspumpen und Infusionsreglern (IEC 60601-2-24:2012)

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

The text of document 62D/1026/FDIS, future edition 2 of IEC 60601-2-24, prepared by SC 62D "Electromedical equipment", of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-24:2015.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2016-01-14
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2018-04-14

This document supersedes EN 60601-2-24:1998.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive 93/42/EEC, see informative Annex ZZ, which is an integral part of this document.

Endorsement notice

The text of the International Standard IEC 60601-2-24:2012 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following note has to be added for the standard indicated :

IEC 61000-4-2	NOTE	Harmonized as EN 61000-4-2.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 When an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

Annex ZA of EN 60601-1:2006 applies, except as follows:

Publication	Year	Title	EN/HD	Year
Replacement in Annex ZA of EN 60601-1:2006:				
IEC 60601-1-2 (mod)	2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	2007
-	-		+ corrigendum Mar.	2010
IEC 60601-1-6	2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	EN 60601-1-6	2010
IEC 60601-1-8	2006	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	EN 60601-1-8	2007
-	-		+ corrigendum Mar.	2010
Addition to Annex ZA of EN 60601-1:2006:				
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
-	-		+ corrigendum Mar.	2010
+ A1	2012		+ A1	2013
-	-		+ A1/AC	2014
-	-		+ A12	2014
ISO 3696	1987	Water for analytical laboratory use - Specification and test methods	EN ISO 3696	1995
ISO 7864	-	Sterile hypodermic needles for single use	EN ISO 7864	-
ISO 8536-4	-	Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed	EN ISO 8536-4	-

Annex ZZ
(informative)

Coverage of Essential Requirements of EU Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and within its scope the Standard covers all relevant essential requirements given in Annex I of EU Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EU Directives can be applied to the products falling within the scope of this standard.

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International standard IEC 60601-2-24 has been prepared by IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition of IEC 60601-2-24 published in 1998. This edition constitutes a technical revision according to IEC 60601-1:2005+A1:2012 with new clause numbering, including usability and alarms.

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

FDIS	Report on voting
62D/1026/FDIS	62D/1039/RVD

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

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

In this standard, the following print types are used:

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

In referring to the structure of this standard, the term

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

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

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

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

- "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;
- "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- "may" is used to describe a permissible way to achieve compliance with a requirement or test.

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

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

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

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

INTRODUCTION

This particular standard deals with the safety of INFUSION PUMPS and INFUSION CONTROLLERS. The relationship between this particular standard, IEC 60601-1:2005+A1:2012, and the collateral standards 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 MEDICAL ELECTRICAL 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.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers

201.1 Scope, object and related standards

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

201.1.1 Scope

Replacement:

This Particular Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of INFUSION PUMPS and VOLUMETRIC INFUSION CONTROLLERS, hereafter referred to as ME EQUIPMENT.

This standard applies to ADMINISTRATION SETS insofar as their characteristics influence the BASIC SAFETY or ESSENTIAL PERFORMANCE of INFUSION PUMPS and VOLUMETRIC INFUSION CONTROLLERS. However this standard does not specify requirements or tests for other aspects of ADMINISTRATION SETS

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

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the general standard.

This particular standard specifies the requirements for ENTERAL NUTRITION PUMPS, INFUSION PUMPS, INFUSION PUMPS FOR AMBULATORY USE, SYRINGE OR CONTAINER PUMPS, VOLUMETRIC INFUSION CONTROLLERS and VOLUMETRIC INFUSION PUMPS, as defined in 201.3.204, 201.3.206, 201.3.207, 201.3.220, 201.3.222 and 201.3.223.

These particular standard does not apply to the following:

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

b) devices for extracorporeal circulation of blood;

c) implantable devices;

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

e) ME 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);

f) devices covered by ISO 28620.

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[1] The general standard is IEC 60601-1:2005+A1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for ENTERAL NUTRITION PUMPS, INFUSION PUMPS, INFUSION PUMPS FOR AMBULATORY USE, SYRINGE OR CONTAINER PUMPS, VOLUMETRIC INFUSION CONTROLLERS and VOLUMETRIC INFUSION PUMPS, as defined in 201.3.204, 201.3.206, 201.3.207, 201.3.220, 201.3.222 and 201.3.223.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-2:2007, IEC 60601-1-6:2010 and IEC 60601-1-8:2006 apply as modified in Clauses 202, 206 and 208 respectively. IEC 60601-1-3 does not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

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

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

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

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

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

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

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

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

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

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

201.2 Normative references

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

Replacement:

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

IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*

IEC 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

Addition:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
Amendment 1:2012

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

ISO 7864, *Sterile hypodermic needles for single use*

ISO 8536-4, *Infusion equipment for medical use – Part 4: Infusion sets for single use, gravity feed*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005+A1:2012, apply, except as follows:

NOTE An index of defined terms is found beginning on page 57.

Replacement:

201.3.8
APPLIED PART
part of ME EQUIPMENT, including the infusion liquid pathway, that in NORMAL USE necessarily comes into physical contact with the PATIENT for ME EQUIPMENT to perform its function

Addition:

201.3.201
ADMINISTRATION SET
accessory that convey(s) liquid from the supply via the ME EQUIPMENT to the PATIENT

201.3.202
ADMINISTRATION SET CHANGE INTERVAL
time recommended by the MANUFACTURER of the ME EQUIPMENT for using the ADMINISTRATION SET

201.3.203
INTENDED BOLUS
discrete quantity of liquid which is intended to be delivered by the ME EQUIPMENT

201.3.204
ENTERAL NUTRITION PUMP
INFUSION PUMP where the liquid is used for enteral nutrition

201.3.205
FREE FLOW
unintended flow to a PATIENT through an ADMINISTRATION SET which is not controlled by the INFUSION PUMP, for example, due to the unintended effects of gravity/pressure by the removal of the ADMINISTRATION SET from the INFUSION PUMP

201.3.206
INFUSION PUMP
ME EQUIPMENT intended to regulate the flow of liquids into the PATIENT under pressure generated by the pump

Note 1 to entry: The INFUSION PUMP may provide one or more of the following types of flow:

– type 1: continuous infusion;

– type 2: non-continuous infusion;

– type 3: discrete delivery of a bolus;

– type 4: PROFILE PUMP;

201.3.207
INFUSION PUMP FOR AMBULATORY USE
INFUSION PUMP intended to be carried continuously by the PATIENT

201.3.208
INTERMEDIATE RATE
test rate for the comparison of different kind of pumps

Note 1 to entry: The specific level of the rate differs for various types of equipment:

– for VOLUMETRIC INFUSION PUMP and VOLUMETRIC INFUSION CONTROLLER, set the rate to 25 ml/h;

– for SYRINGE OR CONTAINER PUMP, set the rate to 5 ml/h;

– for INFUSION PUMPS FOR AMBULATORY USE, set the rate specified by the MANUFACTURER as typical for the ME EQUIPMENT.

201.3.209
KEEP OPEN RATE
KOR
low predetermined rate(s) to which the INFUSION PUMP reverts under specified conditions with the object of keeping the PATIENT LINE open

Note 1 to entry: The abbreviation KVO (Keep-Vein-Open) is commonly used as a synonym of KOR.

201.3.210
MAXIMUM INFUSION PRESSURE
maximum pressure which can be generated by the INFUSION PUMP under conditions of total occlusion at the end of the PATIENT LINE

201.3.211
MINIMUM RATE
lowest rate selectable by the OPERATOR, but not less than 1 ml/h

*** 201.3.212**
MAXIMUM SELECTABLE RATE
highest rate selectable by the OPERATOR if higher than the INTERMEDIATE RATE

*** 201.3.213**
MINIMUM SELECTABLE RATE
lowest rate selectable by the OPERATOR if lower than the MINIMUM RATE

201.3.214
OCCLUSION ALARM THRESHOLD
value of the physical quantity at which the occlusion alarm is activated

201.3.215
PATIENT END
that end of the PATIENT LINE where connection to the PATIENT takes place

201.3.216
PATIENT LINE
that part of the ADMINISTRATION SET between the ME EQUIPMENT and the PATIENT

201.3.217
REGION OF CONTROL
that part of the ME EQUIPMENT within which flow regulation, flow shut-off or air detection occurs, within the body of the ME EQUIPMENT or remotely

201.3.218
PROFILE PUMP
INFUSION PUMP intended for controlled infusion of liquids into the PATIENT by means of a programmed sequence of delivery rates

201.3.219
SUPPLY LINE
that part of the ADMINISTRATION SET between the liquid supply and the ME EQUIPMENT

201.3.220
SYRINGE OR CONTAINER PUMP
INFUSION PUMP 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/bag is emptied by positive pressure applied to the cartridge/bag) in which the delivery rate is indicated in volume per unit of time or units related to drug dosage.

201.3.221
UNINTENDED BOLUS
unintended discrete quantity of liquid which is delivered after release of an occlusion

201.3.222
VOLUMETRIC INFUSION CONTROLLER
ME EQUIPMENT intended to regulate the flow of liquid into the PATIENT under positive pressure generated by gravitational force in which the delivery rate is indicated by the ME EQUIPMENT in volume per unit of time

201.3.223
VOLUMETRIC INFUSION PUMP
INFUSION PUMP in which the delivery rate is indicated in volume per unit of time or units related to drug dosage, but excluding SYRINGE OR CONTAINER PUMPS

201.4 General requirements

Clause 4 of the general standard applies except as follows.

201.4.3 ESSENTIAL PERFORMANCE

Additional subclause:

201.4.3.101 Additional ESSENTIAL PERFORMANCE requirements

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

Table 201.101 – Distributed ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
Accuracy tests for VOLUMETRIC INFUSION CONTROLLERS, VOLUMETRIC INFUSION PUMPS and SYRING OR CONTAINER PUMPS	201.12.1.102
Accuracy tests for INFUSION PUMPS FOR AMBULATORY USE type 1	201.12.1.103
Accuracy tests for INFUSION PUMP FOR AMBULATORY USE type 2	201.12.1.104
Accuracy tests for INFUSION PUMP type 3	201.12.1.105
Accuracy tests for INFUSION PUMP type 4	201.12.1.106
Accuracy tests for INFUSION PUMP type 5	201.12.1.107
Protection against UNINTENDED BOLUS volumes and occlusion	201.12.4.4.104
ALARM SIGNALS of HIGH PRIORITY according to Table 208.101 NOTE For ALARM CONDITIONS resulting from ME EQUIPMENT failure no EMC and environmental testing is necessary.	208.6.1.2.101

201.4.7 * SINGLE FAULT CONDITION for ME EQUIPMENT

Addition:

SINGLE FAULT CONDITIONS occurring in those protective systems specified in 201.12.4.4.101, 201.12.4.4.102, 201.12.4.4.105 and 201.12.4.4.107 shall become obvious to the OPERATOR within the ADMINISTRATION SET CHANGE INTERVAL.

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

1) a safety system check initiated and controlled by the ME 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 ME 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 the 21st dashed item of 201.7.9.2.101).

The following are not regarded as SINGLE FAULT CONDITIONS, but are regarded as NORMAL 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 drop chamber;
– air in the SUPPLY LINE or that part of the ME EQUIPMENT within which flow regulation, flow shut-off or air detection occurs;
– pulling on the PATIENT LINE (see ISO 8536-4).

201.5 General requirements for testing of ME EQUIPMENT

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

201.5.2 Number of samples

Addition:

The MANUFACTURER shall define the number of samples of INFUSION PUMP / INFUSION CONTROLLERS and ADMINISTRATION SET(S) with regard to accuracy in the technical documentation.

Compliance is checked by review of the technical documentation

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies, except as follows:

201.6.6 Mode of operation

Replacement

ME EQUIPMENT shall be classified for CONTINUOUS OPERATION.

201.7 ME EQUIPMENT identification, marking and documents

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

201.7.2.1 Minimum requirements for marking on ME EQUIPMENT and on interchangeable parts

Addition:

The ME EQUIPMENT shall be marked with an arrow or other appropriate symbol indicating the correct direction of flow if the ADMINISTRATION SET can be incorrectly loaded;

Compliance is checked by inspection.

201.7.2.4 ACCESSORIES

Addition:

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 ME EQUIPMENT, then relevant markings shall be fixed or indicated in a prominent place on the ME EQUIPMENT which either identify those conditions or provide location of such information.

Compliance is checked by inspection.

201.7.9.2 Instructions for use

Additional subclause:

201.7.9.2.101 Additional instructions for use

The instructions for use shall also include the following:

- the INTENDED USE including environment conditions;
- a warning of the consequences of the use of unsuitable ADMINISTRATION SET(S);
- permitted ME EQUIPMENT orientation and methods and precautions concerning its mounting, for example, stability on a pole, if applicable;
- * instructions regarding ADMINISTRATION SET CHANGE INTERVAL to maintain the specified performance;
- 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;
- where gravity is relevant to performance, the acceptable height range of the liquid container above the PATIENT and/or pump;
- the means provided to protect the PATIENT from air infusion;
- a statement of the MAXIMUM INFUSION PRESSURE generated by the ME EQUIPMENT;
- a statement of the OCCLUSION ALARM THRESHOLD of the ME EQUIPMENT;
- a statement of the maximum time for activation of the occlusion alarm when the ME EQUIPMENT is operating at the MINIMUM RATE, INTERMEDIATE RATE and the MINIMUM SELECTABLE RATE and at the minimum and maximum selectable OCCLUSION ALARM THRESHOLD (see 201.12.4.4.104). The MANUFACTURER shall also state that temperature and l length of ADMINISTRATION SET affect the time, if applicable;
- a statement of the UNINTENDED BOLUS at the INTERMEDIATE RATE at the minimum and maximum OCCLUSION ALARM THRESHOLDS (see also 201.12.4.4.104);
- a statement regarding management of the entrapped UNINTENDED BOLUS before occlusion release;
- precautions required with drop detectors, for example with respect to placement, cleanliness, liquid level, ambient light;
- *the typical operating time when the ME EQUIPMENT is operating from the INTERNAL ELECTRICAL POWER SOURCE at the INTERMEDIATE RATE and, for VOLUMETRIC INFUSION PUMPS and VOLUMETRIC INFUSION CONTROLLERS, also at the MAXIMUM SELECTABLE RATE with a new and fully charged battery;
- a statement of KEEP OPEN RATE(S), and when initiated;
- a list of alarms and their operating conditions;
- *if applicable, a warning that under certain circumstances the specified accuracy may not be maintained and details of those circumstances.
- *reference to a guide on the HAZARDS associated with the interconnection of other infusion systems or ACCESSORIES to the PATIENT LINE;
- the rate obtained when the prime/purge or BOLUS control is operated, and a statement of any alarm disabled;
- the selectable rate range and the increments of selection;

- if applicable, guidance on tests to permit the OPERATOR to check the correct functioning of alarm(s) and the operational safety of the ME EQUIPMENT;
- data as evaluated by the test methods of 201.12.1.102 to 201.12.1.109 at the rates indicated in Table 201.102, including an explanation for the OPERATOR of the data presentation;
- *the maximum volume that may be infused under SINGLE FAULT CONDITIONS;
- a list of the allowed ADMINISTRATION SET(S) with their stated accuracy in accordance with the test methods mentioned in 201.12.1;
- if changing between different allowed ADMINISTRATION SETS can result in an unacceptable RISK if no changes are made to the ME EQUIPMENT, a statement regarding the procedure to be followed to guarantee the stated accuracy shall be included;
- the range of infusion rates and the conditions (e.g. temperature) for which the stated accuracy is valid;
- a list of ACCESSORIES (e.g. drop sensor) for use with the ME EQUIPMENT which are necessary to maintain the accuracy stated in accordance with the test methods mentioned in 201.12.1 and safe use;
- If applicable, description of how the ME EQUIPMENT operates if communication is lost with the remote control device.

NOTE If the ME EQUIPMENT is part of a ME SYSTEM, the description can be part of the instruction for use of the ME SYSTEM)

- *For PROFILE PUMPS the programmed sequence of delivery rates.

201.7.9.3 Technical description

Additional subclause:

201.7.9.3.101 Additional technical description

The technical description shall include the following:

- *the sensitivity of the air detector, if included to comply with 201.12.4.4.107, over the specified range of rates for a single bubble. For INFUSION PUMP FOR AMBULATORY USE using insulin, the sensitivity of the air detector could e.g. be expressed as the maximum underinfusion until triggering of the air detector (or similar) if air detection is provided.
- if applicable, the PROCESS for calibration of the ME EQUIPMENT;
- a description of any battery charging system;
- a functional description of the means provided to protect the PATIENT from overinfusion and, where applicable, underinfusion resulting from ME EQUIPMENT error or partial or total blockage of the ADMINISTRATION SET;
- The MANUFACTURER shall disclose the identification of ADMINISTRATION SET(S) used for all the tests in this standard,
- If the ME EQUIPMENT cannot be programmed in volume per unit time, and does not display the rate in volume per unit time, the formula for calculating volume per unit time.

Compliance is checked by inspection of the technical description.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies except as follows:

201.8.3 Classification of APPLIED PARTS

Additional subclause:

201.8.3.101 Additional requirements for classification of APPLIED PARTS

APPLIED PARTS of an INFUSION PUMP shall be TYPE BF or TYPE CF APPLIED PARTS.

Check compliance by inspection.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of the general standard applies except as follows:

201.11.6.3 * Spillage on ME EQUIPMENT and ME SYSTEMS

Replacement:

ME EQUIPMENT and ME SYSTEMS requiring the handling of liquids in NORMAL USE shall be so constructed that spillage does not wet parts that could result in a HAZARDOUS SITUATION.

Compliance is checked by the test according to IEC 60529 IPX1 or better:

After these PROCEDURES, the ME EQUIPMENT is to pass the appropriate dielectric strength and LEAKAGE CURRENT tests and is to show no signs of wetting of uninsulated electrical parts or electrical insulation of parts that could result in a HAZARDOUS SITUATION and is to maintain BASIC SAFETY and ESSENTIAL PERFORMANCE

201.11.6.5 Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS

Addition:

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 ME EQUIPMENT in the carrying pouch. Where no such specification exists then the carrying pouch is removed prior to the test.

ME EQUIPMENT shall be appropriate to the environment of use and at least IPX2.

Replacement of compliance statement:

After these PROCEDURES, the ME EQUIPMENT is to show no signs of bridging of insulation (or electrical components) that could result in a HAZARDOUS SITUATION in NORMAL CONDITION or in combination with a SINGLE FAULT CONDITION (based on a visual inspection) followed by the appropriate dielectric strength and LEAKAGE CURRENT tests.

Compliance is checked by inspection and by application of the tests of IEC 60529. Verify that BASIC SAFETY and ESSENTIAL PERFORMANCE are maintained.

201.11.8 Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT

Addition:

Additional subclauses:

201.11.8.101 Power supply/SUPPLY MAINS interruption TECHNICAL ALARM CONDITIONS

201.11.8.101.1 SUPPLY MAINS interruption TECHNICAL ALARM CONDITION

For ME EQUIPMENT that is powered from the SUPPLY MAINS only, if the ME EQUIPMENT is in operation and there is an accidental disconnection or failure of the SUPPLY MAINS the ME EQUIPMENT shall give an ALARM SIGNAL of LOW PRIORITY. Under that condition, the ALARM SIGNAL shall be maintained for at least 3 min or until power is restored, whichever is the less.

NOTE ME EQUIPMENT may stop infusion.

Compliance is checked by inspection and functional tests.

201.11.8.101.2 INTERNAL ELECTRICAL POWER SOURCE depletion TECHNICAL ALARM CONDITION

ME EQUIPMENT which utilizes an INTERNAL ELECTRICAL POWER SOURCE either as a primary or standby supply shall give an ALARM SIGNAL of LOW PRIORITY at least 30 min before delivery ceases due to battery exhaustion.

The visual ALARM SIGNAL indication does not apply to INFUSION PUMP FOR AMBULATORY USE e.g. using insulin.

Compliance is checked by inspection and functional tests when the ME EQUIPMENT is operated at the INTERMEDIATE RATE and with a new and fully charged battery.

If the SUPPLY MAINS and the INTERNAL ELECTRICAL POWER SOURCE both fail the ME EQUIPMENT shall give an ALARM SIGNAL of HIGH PRIORITY and cease delivery. The alarm shall be maintained for the duration of at least 3 min.

This requirement does not apply to INFUSION PUMP FOR AMBULATORY USE e.g. using insulin.

Compliance is checked by inspection and functional test.

201.12 *Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of the general standard applies except as follows:

201.12.1 Accuracy of controls and instruments

Additional subclauses:

201.12.1.101 *General formula

The ME 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 201.12.1.102 to 201.12.1.108, to verify the accuracy of the ME EQUIPMENT according to its defined type and the MANUFACTURER'S

disclosure of accuracy. If the ME EQUIPMENT does not fall into one of the defined categories use the appropriate test from 201.12.1.102 to 201.12.1.108.

Definition of terms given in 201.12.1.102 to 201.12.1.108

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 test period
analysis period T_2	designated as the last hour of the test period
analysis period T_x	the 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)

201.12.1.102 *Accuracy tests for VOLUMETRIC INFUSION CONTROLLERS, VOLUMETRIC INFUSION PUMPS and SYRINGE OR CONTAINER PUMPS

The test apparatus shown in Figures 201.104a and 201.104b is used. Carry out the tests using a test solution of ISO 3696:1987 Class III and installing an unused ADMINISTRATION SET. Set up the ME EQUIPMENT with the test solution in accordance with the MANUFACTURER'S instructions for use.

Ensure that ME 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 201.102 Set the sample interval *S*. Begin the test period simultaneously with starting the ME EQUIPMENT.

Determine the test period T. This test period shall equal the recommended ADMINISTRATION SET CHANGE INTERVAL if there is sufficient fluid in the container. If not, calculate the duration of the test period by dividing the total fluid volume by the rate. Allow the ME EQUIPMENT to run for the test period T.

For VOLUMETRIC INFUSION PUMPS and SYRINGE OR CONTAINER PUMPS repeat the test at the INTERMEDIATE RATE for a period of 120 min at back pressures of ±13,33 kPa (±100 mmHG).

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 mmHG).

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 if the supply container is below the pump mechanism, if applicable.

If the ME EQUIPMENT incorporates a BOLUS facility carry out the tests specified in 201.12.1.106.

If the test of 201.12.1.102 cannot be applied because of design features within the ME EQUIPMENT, apply the most appropriate test from 201.12.1.103 to 201.12.1.108.

Calculate the actual flow Q_i for each sample interval for the analysis period T_0(min) from Equation (1) (see Figure 201.103).

Calculate E_p(max.) and E_p(min.) for the 2 min, 5 min, 11 min, 19 min and 31 min observation windows from Equations (3) and (4) over the analysis period T_1 (min) of the second hour of the test period.

Except for SYRINGE OR CONTAINER PUMPS calculate E_p(max.) and E_p(min.) for the 2 min, 5 min, 11 min, 19 min and 31 min observation windows from Equations (3) and (4) 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.3.3):

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 201.105. 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 (5)) measured over the analysis period T_1 (min) of the second hour of the test period. See example in Figure 201.106.

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.

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 (6)) measured over the analysis period T_2 (min) of the last hour of the test period.

See example in Figure 201.107.

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 OR CONTAINER PUMPS.

- **Formulae**

Calculate flow using the expression:

$$Q_i = \frac{60\,(W_i - W_{i-1})}{S\mathrm{d}}(\mathrm{ml/h}) \qquad (1)$$

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

$$m = \frac{(T_x - P)}{S} + 1 \qquad (2)$$

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:

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

$$E_{\mathrm{p}}(\mathrm{min.}) = \underset{j=1}{\overset{m}{\mathrm{MIN}}}\left[\frac{S}{P} \times \sum_{i=j}^{j+\frac{P}{S}-1} 100 \times \left(\frac{Q_{\mathrm{i}} - r}{r}\right)\right](\%) \quad (4)$$

where

$$Q_{\mathrm{i}} = \frac{60\,(W_{\mathrm{i}} - W_{\mathrm{i-1}})}{S\mathrm{d}}(\mathrm{ml/h})$$

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):

$$A = \frac{100(Q - r)}{r}(\%) \quad (5)$$

where

$$Q = \frac{60\,(W_{\mathrm{j}} - W_{\mathrm{k}})}{T_1\mathrm{d}}(\mathrm{ml/h})$$

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):

$$B = \frac{100(Q - r)}{r}(\%) \quad (6)$$

where

$$Q = \frac{60\,(W_{\mathrm{j}} - W_{\mathrm{k}})}{T_2\mathrm{d}}(\mathrm{ml/h})$$

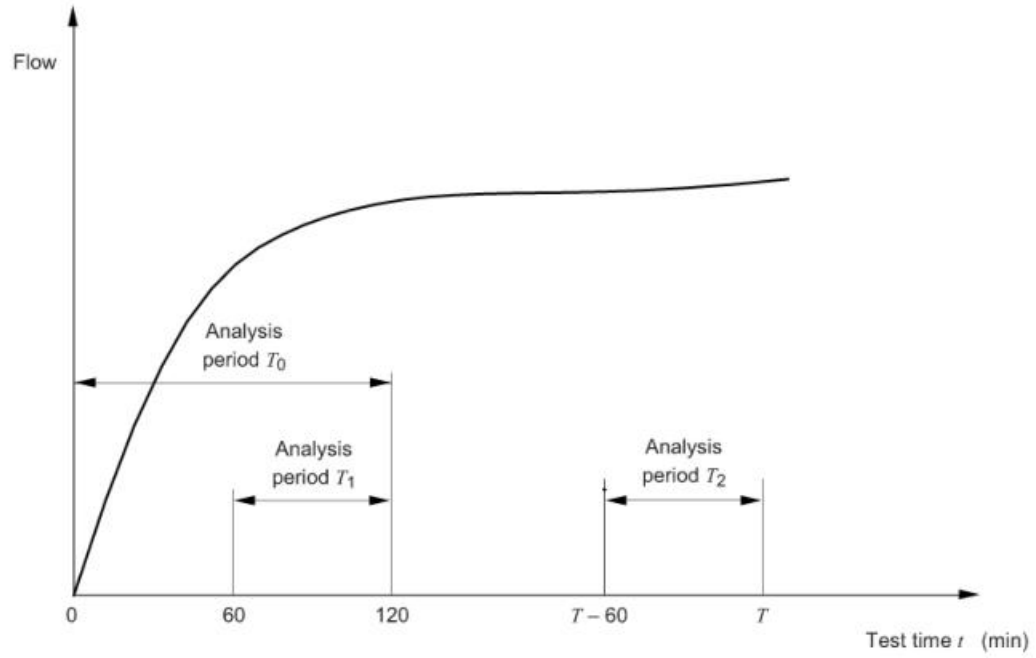
r is the rate (ml/h);

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);

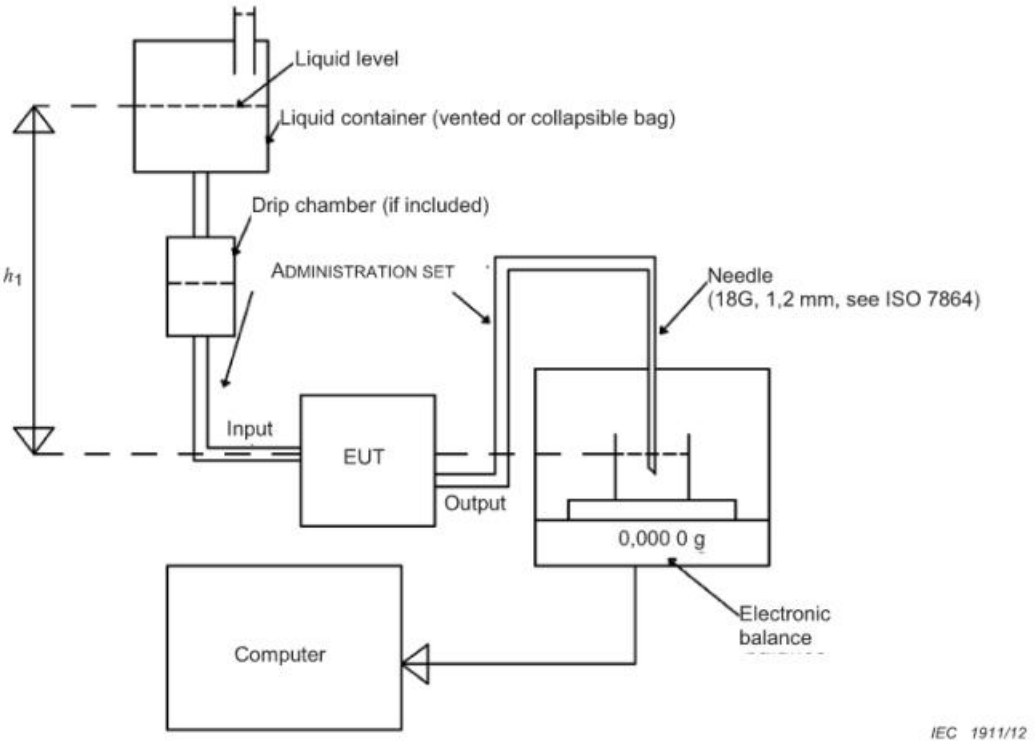
d is the density of water (0,998 g/ml at 20 °C).



T = ADMINISTRATION SET CHANGE INTERVAL

IEC 1910/12

Figure 201.103 – Analysis periods



IEC 1911/12

Figure 201.104a – Test apparatus for VOLUMETRIC INFUSION PUMPS and VOLUMETRIC INFUSION CONTROLLERS

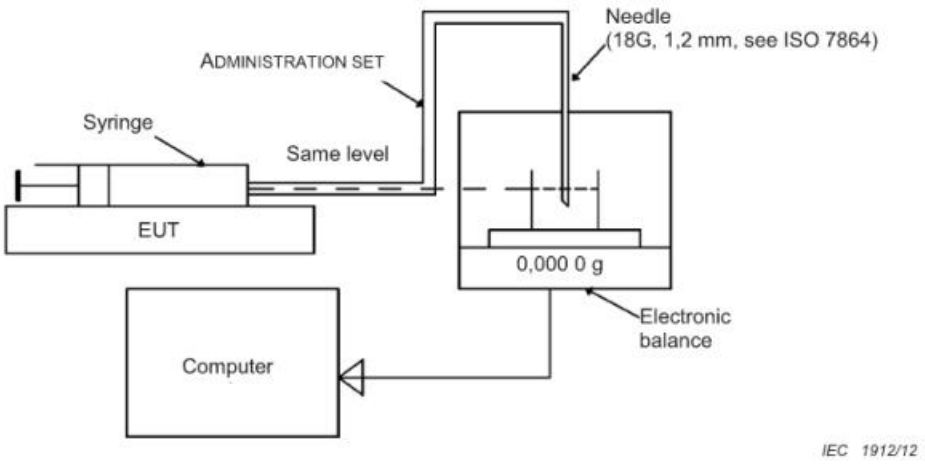


Figure 201.104b – Test apparatus for SYRINGE OR CONTAINER PUMPS

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 (18G, 1,2 mm, ISO 7864) shall be positioned below the liquid surface.

The mean centre line of the pumping chamber to be at the same height as the tip of the needle (18G, 1,2 mm, ISO 7864).

The needle (ISO 7854) I.D. and length should be chosen to produce a pressure difference of 0.20 (±0.10) mmHg based on the Hagen-Poiseuille formula (using a rate of 25 ml/h and viscosity of 0.01 poise).

Figure 201.104 – Test apparatuses for different types of INFUSION PUMPS

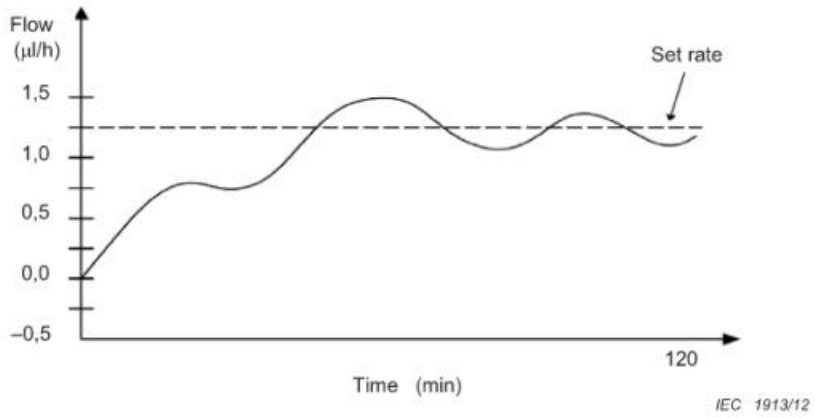


Figure 201.105 – Start-up graph plotted from data gathered during the first 2 h of the test period

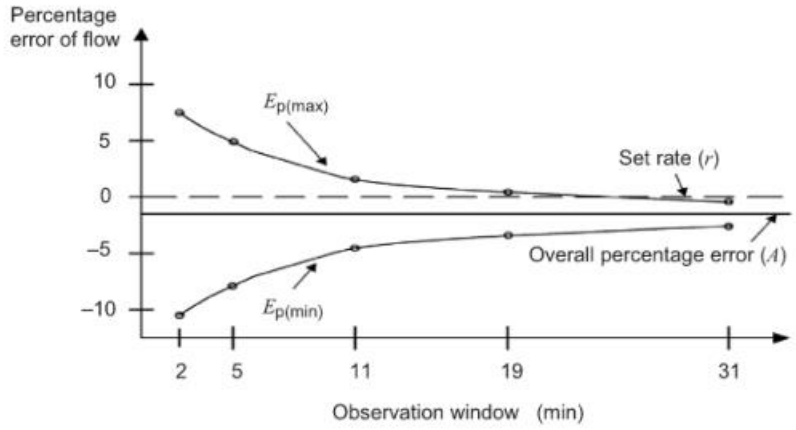


Figure 201.106 – Trumpet curve plotted from data gathered during the second hour of the test period

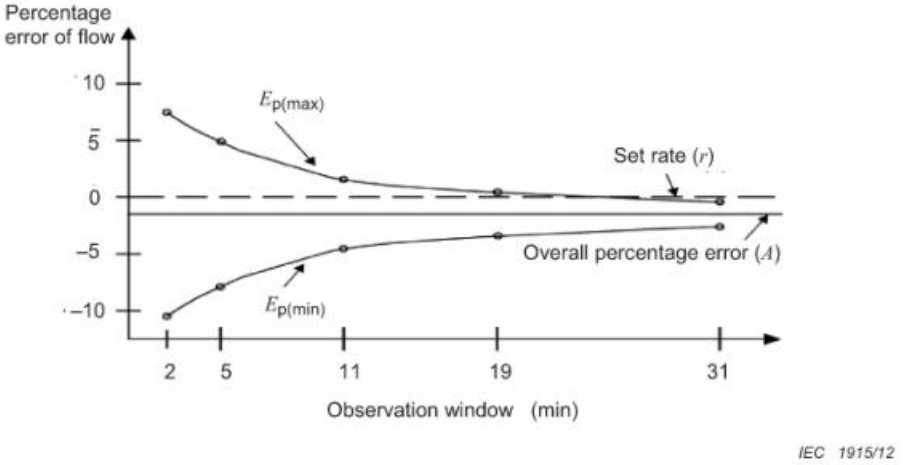


Figure 201.107 – Trumpet curve plotted from data gathered during the last hour of the ADMINISTRATION SET CHANGE INTERVAL

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

The test apparatus shown in Figure 201.102b is used. Carry out the tests using a test solution of ISO 3696:1987 class III or a liquid which can be expected to give similar test results and installing an unused ADMINISTRATION SET. Set up the ME EQUIPMENT in accordance with the MANUFACTURER'S instructions for use. Prime the ADMINISTRATION SET and set the ME EQUIPMENT for the INTERMEDIATE RATE. Start the ME EQUIPMENT. Set the sample interval S to 15 min. Allow the ME EQUIPMENT to run for a time equivalent to half the container volume, or 24 h, whichever is the shorter as a stabilization period T_1 (min). Continue the test without stopping the ME 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 (7) for every two successive samples over the stabilization period T_1.

Calculate E_p(max.) and E_p(min.) for the 15 min, 60 min, 150 min, 330 min, 570 min and 930 min observation windows from Equations (9) and (10) 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 201.108 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 (11). 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 201.109 as an example.

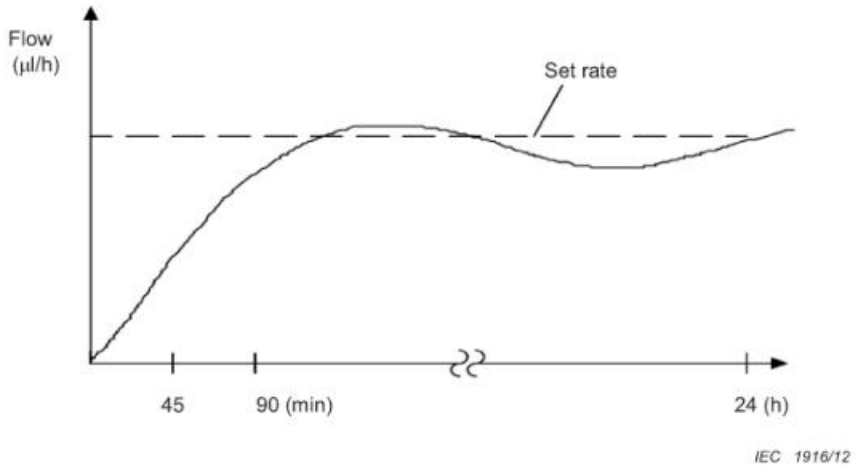


Figure 201.108 – Start-up graph over the stabilization period

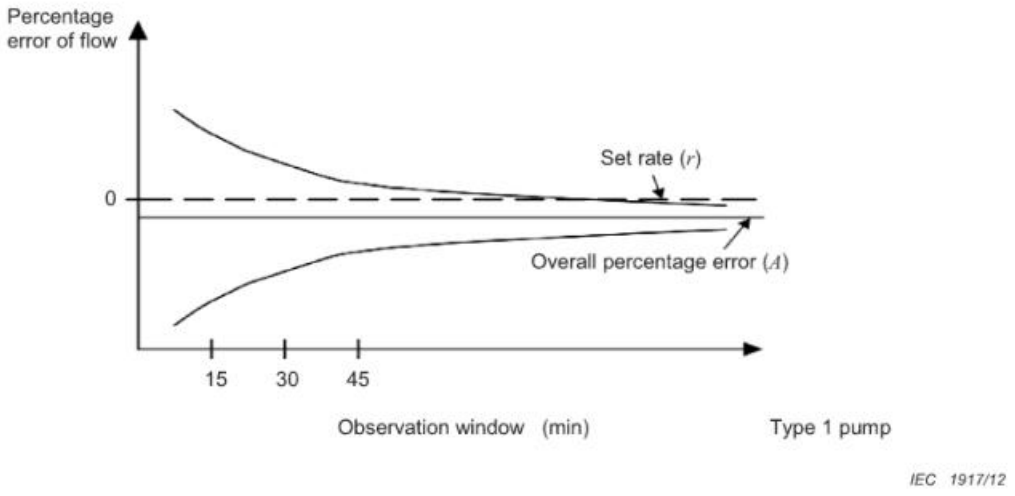


Figure 201.109 – Trumpet curve plotted from data at the end of the stabilization period

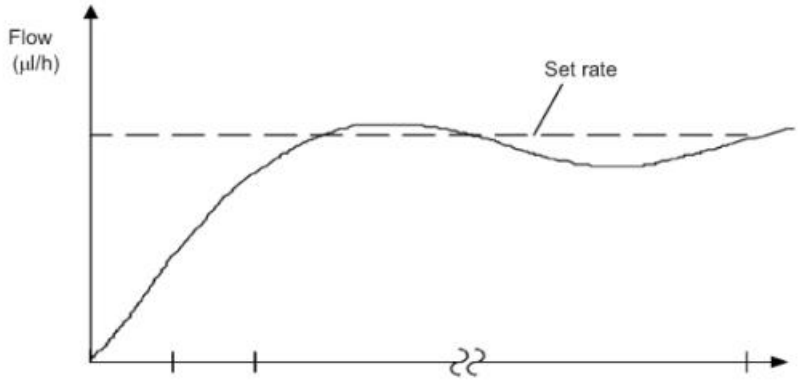


Figure 201.110 – Start-up curve over the stabilization period for quasi-continuous output pumps

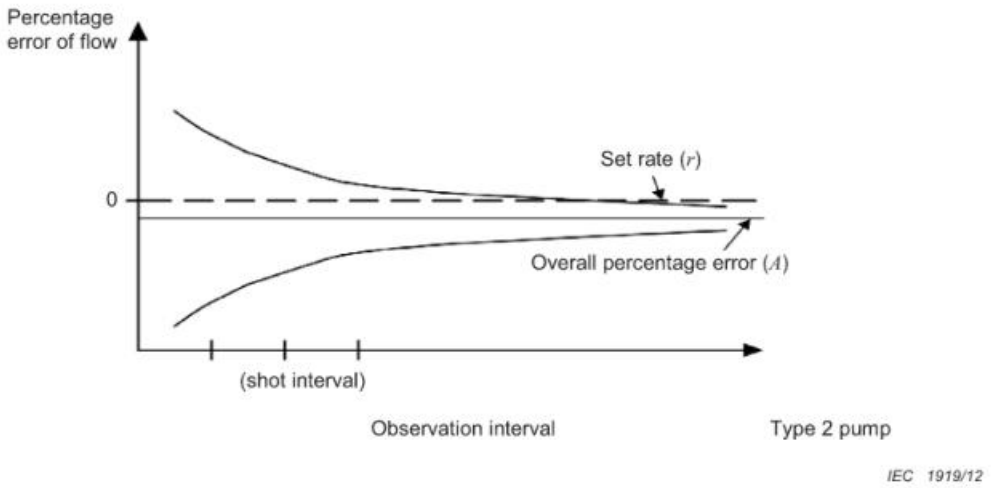


Figure 201.111 – Trumpet curve plotted from data at the end of the stabilization period for quasi-continuous pumps

- **Formulae**

Calculate flow using the expression:

$$Q_{\mathrm{i}} = \frac{60\,(W_{2\mathrm{i}} - W_{2(\mathrm{i}-1)})}{2\mathrm{d}S}(\mu\mathrm{l/h}) \qquad (13)$$

where

i 1, 2.. T_1 /2S;

W_{i} is the $_i^{\mathrm{th}}$ 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 min, 60 min, 150 min, 330 min, 570 min and 930 min, within the analysis period T_2, there are a maximum of m observation windows, such that:

$$m = \frac{(T_2 - P)}{S} + 1 \tag{14}$$

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;

$$E_p(\text{max.}) = \underset{j=1}{\overset{m}{\text{MAX}}} \left[\frac{S}{P} \times \sum_{i=j}^{j+\frac{P}{S}-1} 100 \times \left(\frac{Q_i - r}{r} \right) \right] (\%) \tag{15}$$

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

where

$$Q_i = \frac{60\,(W_i - W_{i-1})}{S\text{d}} (\text{ml/h})$$

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:

$$A = \frac{100(Q - r)}{r} (\%) \tag{17}$$

where

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

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).

201.12.1.104 *Accuracy tests for INFUSION PUMP FOR AMBULATORY USE type 2

The test apparatus shown in Figure 201.104b is used. Carry out the tests using a test solution of ISO 3696:1987 class III or a liquid which can be expected to give similar test results and installing an unused ADMINISTRATION SET. Set up the ME 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:

$$S = kI \tag{18}$$

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

$$S = kI \tag{19}$$

where

S is the sample interval;

I is the shot cycle;

k is the minimum integer constant giving kI 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 ME EQUIPMENT for the INTERMEDIATE RATE.

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

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

Choose any integer n so that:

$$nS \approx 30 \text{ (min)} \tag{20}$$

where

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

n is the integer constant.

Calculate the mean flow from Equation (21) for every successive nS samples, 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 (23) and (24) 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 201.110 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 (25)).

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 201.111 as an example.

- **Formulae**

Calculate flow using the expression:

$$Q_i = \frac{60\,(W_{ni} - W_{n(i-1)})}{ndS} \text{(µl/h)} \tag{21}$$

where

i = 1, 2.. T_1/nS;

W_i is the ith 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) = (kImin);

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:

$$m = \frac{(T_2 - P)}{S} + 1 \tag{22}$$

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:

$$E_p(\text{max.}) = \underset{j=1}{\overset{m}{\text{MAX}}} \left[\frac{S}{P} \times \sum_{i=j}^{j+\frac{P}{S}-1} 100 \times \left(\frac{Q_i - r}{r} \right) \right] (\%) \quad (23)$$

$$E_p(\text{min.}) = \underset{j=1}{\overset{m}{\text{MIN}}} \left[\frac{S}{P} \times \sum_{i=j}^{j+\frac{P}{S}-1} 100 \times \left(\frac{Q_i - r}{r} \right) \right] (\%) \quad (24)$$

where

$$Q_i = \frac{60\,(W_i - W_{i-1})}{S\text{d}} (\mu\text{l/h})$$

W_i is the ith 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:

$$A = \frac{100(Q - r)}{r} (\%) \quad (25)$$

where

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

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).

201.12.1.105 *Accuracy tests for INFUSION PUMP type 3

The test apparatus shown in figures 201.104a or 201.104b is used (as appropriate) using a test solution of ISO 3696:1987 class III or a liquid which can be expected to give similar test results and installing an unused ADMINISTRATION SET. Set up the ME EQUIPMENT with the recommended ADMINISTRATION SET in accordance with the MANUFACTURER'S instructions for use. Set the ME EQUIPMENT to supply a BOLUS at the minimum setting. Start the ME EQUIPMENT and weigh 25 successive BOLUS deliveries either demanded manually or by programme.

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 ME EQUIPMENT at the maximum BOLUS setting.

201.12.1.106 *Accuracy tests for INFUSION PUMP type 4

INFUSION PUMP type 4 shall be tested according to 201.12.1.103, 201.12.1.104 and 201.12.1.105 as appropriate.

NOTE Correction factors may be applicable to INFUSIONPUMPS 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.

201.12.1.107 *Accuracy tests for INFUSION PUMP type 5

INFUSION PUMP type 5 shall be tested according to 201.12.1.102 to 201.12.1.105, as appropriate.

Table 201.102 – Set rates, BOLUS volumes and test apparatus for the accuracy tests of 12.1.102 to 12.1.107

ME EQUIPMENT	Set rates		BOLUS		Test	
	Minimum	Inter-mediate	Minimum	Maximum	Apparatus (figure)	Subclause
VOLUMETRIC INFUSION CONTROLLER	Used	Used	Not used	Not used	201.104a), 201.104b)	201.12.1.102
VOLUMETRIC INFUSION PUMP	Used	Used	Used	Used	201.104a), 201.104b)	201.12.1.102, (201.12.1.105)
SYRINGE OR CONTAINER PUMP	Used	Used	Used	Used	201.104b)	201.12.1.102, (201.12.1.105)
INFUSION PUMPS FOR AMBULATORY USE type 1	Used	Used	Not used	Not used	201.104b)	201.12.1.103
INFUSION PUMPS FOR AMBULATORY USE Type 2	Not used	Used	Not used	Not used	201.104b)	201.12.1.104
VOLUMETRIC, INFUSION PUMP, or SYRINGE OR CONTAINER PUMP or INFUSION PUMP FOR AMBULATORY USE type 3	Not used	Not used	Used	Used	201.104a), 201.104b)	201.12.1.105
VOLUMETRIC, INFUSION PUMP, or SYRINGE OR CONTAINER PUMP or INFUSION PUMP FOR AMBULATORY USE type 4	Used	Used	Used	Used	201.104a), 201.104b)	201.12.1.103 and 201.12.1.105
VOLUMETRIC, INFUSION PUMP, or SYRINGE OR CONTAINER PUMP or INFUSION PUMP FOR AMBULATORY USE type 5	Used	Used	Used	Used	201.104a), 201.104b)	201.12.1.103 and 201.12.1.105

201.12.4.1 Intentional exceeding of safety limits

Addition:

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

201.12.4.4 Incorrect output

Additional subclauses:

201.12.4.4.101 Protection against overinfusion

Means shall be provided in the ME EQUIPMENT to protect against overinfusion under SINGLE FAULT CONDITIONS. An ALARM SIGNAL according to Table 208.101 shall be initiated in the event of overinfusion and the ME EQUIPMENT shall either cease delivery of infusion liquid or reduce the delivery rate to the KEEP OPEN RATE or less.

SINGLE FAULT CONDITIONS occurring in those protective systems specified shall become obvious to the OPERATOR within the ADMINISTRATION SET CHANGE INTERVAL.

Compliance is checked by inspection and functional tests.

201.12.4.4.102 *Protection against overinfusion FREE FLOW conditions

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

SINGLE FAULT CONDITIONS occurring in those protective systems specified shall become obvious to the OPERATOR within the ADMINISTRATION SET CHANGE INTERVAL.

Additional requirements are found in 201.15.102 and 201.15.103.

Compliance is checked by inspection and functional tests if applicable. As an example, a functional test is to allow the flow to stabilize after momentarily lowering the collecting vessel by 50 cm and checking for evidence of FREE FLOW.

201.12.4.4.103 MAXIMUM INFUSION PRESSURE

The ME 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.

201.12.4.4.104 Protection against UNINTENDED BOLUS volumes and by occlusion

Means shall be provided in the ME EQUIPMENT to protect the PATIENT from underinfusion resulting from occlusion.

NOTE An acceptable method of complying with this requirement is at OCCLUSION ALARM THRESHOLD to activate an ALARM SIGNAL of HIGH PRIORITY and terminate the infusion liquid flow.

Means shall be provided in the ME EQUIPMENT to protect the PATIENT from UNINTENDED BOLUS following activation of the ALARM SIGNAL for occlusion.

Compliance is checked by the following test:

This test applies only to INFUSION PUMPS, VOLUMETRIC INFUSION PUMPS, INFUSION PUMPS FOR AMBULATORY USE and SYRINGE OR CONTAINER PUMPS.

The test apparatus shown in Figure 201.112 is used. Carry out the tests using a test solution of ISO 3696:1987 class III or using the existing drug in the INFUSION PUMP, if the drug is prefilled by the MANUFACTURER. Perform the test under normal conditions (20 °C ± 2 °C, 65 % ± 5 % RH). Operate the ME 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 minimum OCCLUSION ALARM THRESHOLD. Connect the PATIENT END of the PATIENT LINE to the stopcock. Open the stopcock to the collecting vessel. Start the ME EQUIPMENT and allow the flow to become constant. Switch the stopcock and measure the pressure at the OCCLUSION ALARM THRESHOLD. Measure the time taken from switching the stopcock to activation of the occlusion alarm.

If an automatic bolus reduction feature is available, allow this function to complete.

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

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

If an automatic bolus reduction feature can be disabled repeat the test with this feature disabled.

If any OPERATOR action is given for the eleventh dashed item of 201.7.9.2.101 a test shall also be conducted of the means provided by the ME EQUIPMENT to release unreleased UNINTENDED BOLUS. This consists of performing the release as described before measuring the amount of the UNINTENDED BOLUS remaining.

Verify by volume or mass that the result of the test is in accordance with the requirements of 201.12.4.4.101 and 201.12.4.4.102 and the disclosure statement in the ACCOMPANYING DOCUMENTS required by the eighth to eleventh dashed items of 201.7.9.2.101).

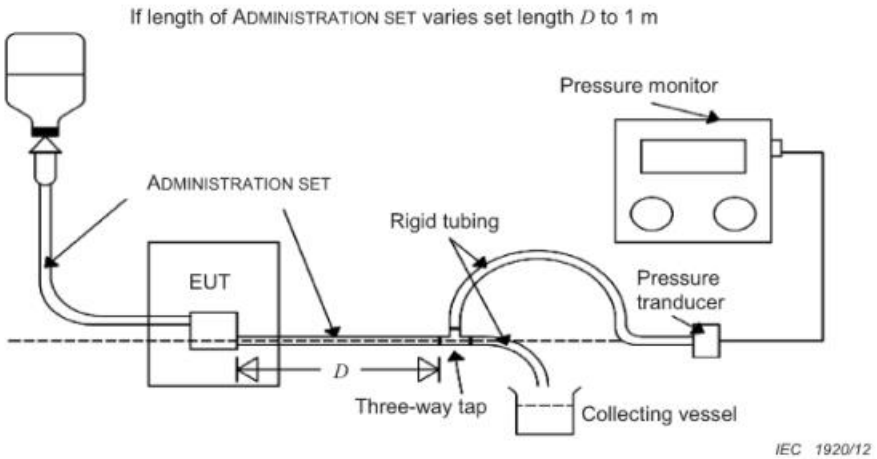


Figure 201.112 – Test apparatus to determine the OCCLUSION ALARM THRESHOLD and BOLUS volumes

201.12.4.4.105 Reverse delivery

Any reverse flow shall not cause an unacceptable RISK in NORMAL USE and SINGLE FAULT CONDITION.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

201.12.4.4.106 ME EQUIPMENT and drop sensor orientation

This test applies only to INFUSION PUMPS with a particular ACCESSORY (drop sensor),

Safe operation of the ME EQUIPMENT shall not be affected by:

– the mispositioning or removal of a drop sensor, and
– operating the ME EQUIPMENT with a tilted or incorrectly filled drop chamber.

Under these conditions the ME EQUIPMENT shall either:

– maintain the accuracy of delivery, or
– stop the flow and generate an ALARM SIGNAL according to Table 208.101.

Compliance is checked by the following functional test:

Operate the ME EQUIPMENT in NORMAL USE according to the MANUFACTURER'S instructions for use. Select any rate. Tilt the drop 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 drop chamber.

201.12.4.4.107 *Protection against air infusion

This requirement does not apply to INFUSION PUMPS FOR AMBULATORY USE using a subcutaneous access, ENTERAL NUTRITION PUMPS and SYRINGE OR CONTAINER PUMPS.

The ME EQUIPMENT shall protect the PATIENT from air infusion which can cause an unacceptable RISK due to air embolism.

Compliance is checked by inspection and functional tests in accordance with the MANUFACTURER'S specification (see first dashed item of 201.7.9.3.101).

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

Compliance is checked by inspection and functional test.

SINGLE FAULT CONDITIONS occurring in the protective system of the ME EQUIPMENT shall cause the cessation of delivery and the generation of an ALARM SIGNAL according to Table 208.101 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.

201.12.4.4.108 ADMINISTRATION SETS – Operational characteristics

Should the MANUFACTURER allow the use of a range of ADMINISTRATION SETS with different operational characteristics, then the ME EQUIPMENT shall not start infusion until

– either the type of ADMINISTRATION SET has been detected automatically, or
– the OPERATOR has identified the type of ADMINISTRATION SET

to prevent incorrect output.

Compliance is checked by inspection and functional test.

201.12.4.4.109 Protection against underinfusion

The MANUFACTURER shall address in the RISK MANAGEMENT PROCESS RISKS associated with underinfusion due to any cause including blockage of the ADMINISTRATION SET.

Compliance is checked by inspection of the risk management file

201.13 HAZARDOUS SITUATIONS and fault conditions

Clause 13 of the general standard applies, except as follows:

201.13.2.6 *Leakage of liquid

Replacement:

ME 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 ME 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 ME EQUIPMENT in the least favourable orientation of NORMAL USE and according to the MANUFACTURER'S instructions for use. By means of a pipette apply drops of the test solution specified by the MANUFACTURER 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 unfavourable.

Immediately after application of the test solution, carry out the test(s) from 201.12.1.102 to 201.12.1.107 according to the classification of the ME EQUIPMENT, at the INTERMEDIATE RATE only. If the ME EQUIPMENT does not fall into one of the defined categories then use the appropriate test from 201.12.1.102 to 201.12.1.107 ((see 201.12.1)). Carry out the tests of 201.12.4.4.106 and 201.12.4.4.107. Switch off the ME 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 worst case test solution which consists of a 50 % dextrose solution or as indicated in the RISK MANAGEMENT FILE of the MANUFACTURER.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard applies.

201.15 Construction of ME EQUIPMENT

Clause 15 of the general standard applies, except as follows:

201.15.4.4 Indicators

Addition at the end of the first paragraph:

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

An indicator light (or means other than marking) shall be provided to indicate that the pump is operated from an INTERNAL ELECTRICAL POWER SOURCE. This requirement does not apply if the pump is powered only by an INTERNAL ELECTRICAL POWER SOURCE.

ME EQUIPMENT powered by an INTERNAL ELECTRICAL POWER SOURCE shall incorporate means to check the battery state at any time by the OPERATOR. Excluded are INFUSION PUMPS FOR AMBULATORY use with a subcutaneous access.

Additional subclauses

201.15.101 Fitting of the syringe/container

If a syringe/container can be fitted by the OPERATOR, means shall be provided to ensure correct clamping and location of a syringe/container and pumping mechanism to prevent FREE FLOW.

In the event of incorrect location of a syringe/container the pump shall not start and an ALARM SIGNAL according to Table 208.101 shall be activated.

Means shall be provided to prevent FREE FLOW under SINGLE FAULT CONDITIONS.

An ALARM SIGNAL according to Table 208.101 shall be activated, if an attempt is made to remove the syringe/container while the INFUSION PUMP is running.

Compliance is checked by inspection and the following test

After the syringe/container is installed, it is disturbed just sufficiently to trigger the ALARM SIGNAL according to Table 208.101. Confirm that FREE FLOW does not occur.

ME EQUIPMENT shall be so designed that no unacceptable RISK for the PATIENT can occur due to pulling force on the PATIENT LINE.

Compliance is checked by inspection and by test with a force of 15 N and for 15 s in the worst case condition. Confirm that FREE FLOW does not occur.

201.15.102 Fitting of the ADMINISTRATION SET

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

In the event of incorrect location of the ADMINISTRATION SET the INFUSION PUMP shall not start and deliver fluid and an ALARM SIGNAL according to Table 208.101 shall be activated.

An ALARM SIGNAL according to Table 208.101 shall be activated, if an attempt is made to remove the ADMINISTRATION SET while the INFUSION PUMP is delivering fluid.

An ME EQUIPMENT shall be so designed that there is no unacceptable RISK to the PATIENT due to pulling force on the PATIENT LINE and the SUPPLY LINE, if applicable. The test is performed with a force of 15 N and for 15 s in worst case condition.

Compliance is checked by functional testing. Specify that, after the ADMINISTRATION SET is installed, it is disturbed just sufficiently to trigger the ALARM SIGNAL, and that FREE FLOW does not occur until the ADMINISTRATION SET is moved further.

201.15.103 *Use 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 ALARM SIGNAL according to Table 208.101.

This requirement does not apply to SYRINGE OR CONTAINER PUMPS and INFUSION PUMPS FOR AMBULATORY USE which use syringes or the pumping mechanism is combined with the "container" (fluid displacement and container in the same part), (see 201.12.4.4.102).

ME EQUIPMENT shall be so designed that, if it is accidentally switched off and then switched on again by means of a functional control, there shall be no unacceptable RISK to the PATIENT.

Compliance is checked by inspection and functional test.

201.16 ME SYSTEMS

Clause 16 of the general standard applies.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Clause 17 of the general standard applies.

202 Electromagnetic compatibility – Requirements and tests

IEC 60601-1-2:2007 applies except as follows:

202.6.2.1.3 Operating mode and configuration

Addition:

Protection against UNINTENDED BOLUS volumes and occlusion, and ALARM CONDITIONS regarded as ESSENTIAL PERFORMANCE (see Table 208.101) are tested once after exposure to all relevant immunity test levels.

202.6.2.2.1 Requirements

Replacement:

ME EQUIPMENT shall comply with the requirements of 6.2.1.10 (of IEC 60601-1-2:2007) as modified below at IMMUNITY TEST LEVELS specified in Table 202.101 for air and contact discharge. For this requirement, the following conditions if associated with BASIC SAFETY and ESSENTIAL PERFORMANCE shall apply:

- no permanent DEGRADATION or loss of FUNCTION which is not recoverable or dataloss which could cause an unacceptable RISK shall be observed at any IMMUNITY TEST LEVEL;
- no inappropriate delivery of fluids to the PATIENT shall occur at any IMMUNITY TEST LEVEL;
- at IMMUNITY TEST LEVELS 1,2 and 3, the ME EQUIPMENT shall maintain normal performance within the specification limits;
- at IMMUNITY TEST LEVELS 4, the temporary degradation or loss of function or performance which requires OPERATOR intervention is acceptable.

Table 202.101 – Test levels

Contact discharge		Air discharge	
Level	Test voltage kV	Level	Test voltage kV
1	2	1	2
2	4	2	4
3	6	3	8
4	8	4	15

NOTE Table 202.101 is taken from IEC 61000-4-2:2008 Table 1and modified

Check compliance by application of the tests in 6.2.2.2 [of IEC 60601-1-2:2007]. Evaluate the response of the ME EQUIPMENT or ME SYSTEM during and after these tests in accordance with 6.2.1.10 [of IEC 60601-1-2:2007] as modified in above, considering each discharge individually.

206 Usability

IEC 60601-1-6:2010 applies except as follows:

Additional subclause:

206.101 PRIMARY OPERATING FUNCTIONS

As a minimum, the following shall be considered.

- power on;
- load ADMINISTRATION SET or syringe/container;
- select infusion parameters;
- infusion start;
- alarm notification and operator action(s) to resolve the alarm situation;
- changing infusion parameters;
- infusion stop;
- remove ADMINISTRATION SET or syringe/container;
- power off.

The MANUFACTURER shall determine the complete list of PRIMARY OPERATING FUNCTIONS for the ME EQUIPMENT.

208 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

IEC 60601-1-8:2006 applies except as follows:

208.6.1.2 ALARM CONDITION priority

Additional subclause:

208.6.1.2.101 ALARM CONDITION priorities and related situations

ME EQUIPMENT shall comply with the requirements of Table 208.101.

Table 208.101 – ALARM CONDITION priorities and related situations

Situation	For type of ME EQUIPMENT	ALARM CONDITION priority	Auditory	Visual
ME EQUIPMENT FAILURE	All types of pumps	HIGH PRIORITY	Yes	Yes
Prior end of infusion alarm	SYRINGE OR CONTAINER PUMP, PROFILE PUMP	LOW PRIORITY	Repeating Between 15 s and 30 s interburst interval Three tones Acknowledged by AUDIO PAUSED by a single action of OPERATOR REMINDER SIGNAL.	Yes
End of infusion alarm	PROFILE PUMP SYRINGE OR CONTAINER PUMP, VOLUMETRIC INFUSION CONTROLLER VOLUMETRIC INFUSION PUMP	HIGH PRIORITY	Yes	Yes
Occlusion alarm	PROFILE PUMP, SYRINGE OR CONTAINER PUMP, VOLUMETRIC INFUSION CONTROLLER VOLUMETRIC INFUSION PUMP	HIGH PRIORITY	Yes	Yes
Air in line alarm	PROFILE PUMP, VOLUMETRIC INFUSION CONTROLLER VOLUMETRIC INFUSION PUMP	HIGH PRIORITY	Yes	Yes
Battery alarm	PROFILE PUMP SYRINGE OR CONTAINER PUMP, VOLUMETRIC INFUSION CONTROLLER, VOLUMETRIC INFUSION PUMP ENTERAL NUTRITION PUMP	LOW PRIORITY	Repeating Between 15 s and 30 s interburst interval Three tones Acknowledged by AUDIO PAUSED by on single action of OPERATOR REMINDER SIGNAL.	Yes

Situation	For type of ME EQUIPMENT	ALARM CONDITION priority	Auditory	Visual
ME EQUIPMENT FAILURE	All types of pumps	HIGH PRIORITY	Yes	Yes
No action with the pump	PROFILE PUMP, SYRINGE OR CONTAINER PUMP, VOLUMETRIC INFUSION CONTROLLER, VOLUMETRIC INFUSION PUMP	LOW PRIORITY	Repeating Between 15s and 30s interburst interval Three tones Acknowledged by AUDIO PAUSED by on single action of OPERATOR REMINDER SIGNAL.	Yes

Compliance is checked by inspection and functional tests

208.6.3.3.1 *Characteristics of auditory ALARM SIGNALS

Amendment:

Modification of the first and second rows of Table 4 of IEC 60601-1-8:2006 for INFUSION PUMPS FOR AMBULATORY USE only, as shown in Table 208.102.

Table 208.102 – * Characteristics of the PULSE of auditory ALARM SIGNALS

Characteristic	Value
PULSE FREQUENCY (f_o)	150 Hz to 3 000 Hz
Number of harmonic components in the range 300 Hz to 4 000 Hz	Minimum 1
Effective PULSE duration (t_d) HIGH PRIORITY MEDIUM and LOW PRIORITY	 75 ms to 200 ms 125 ms to 250 ms
RISE TIME (t_r)	10 % – 20 % of t_d
FALL TIME[a] (t_f)	$t_f \leq t_s - t_r$
NOTE The relative sound pressure level of the harmonic components should be within 15 dB above or below amplitude at the PULSE FREQUENCY.	
[a] Prevents overlap of PULSES.	

If a facility to select any alternative scheme of auditory ALARM SIGNAL characteristics is provided, access shall be restricted to the RESPONSIBLE ORGANIZATION, 6.7 of IEC 60601-1-8 shall apply to this facility, and the technical description shall also include a warning to the RESPONSIBLE ORGANIZATION to carry out a RISK assessment before selecting alternative ALARM SIGNALS.

208.6.3.3.2 Volume of auditory ALARM SIGNALS and INFORMATION SIGNALS

Addition:

208.6.3.3.2.101 Volume of auditory ALARM SIGNALS

For other than INFUSION PUMPS FOR AMBULATORY USE, unless the INFUSION PUMP is connected to a DISTRIBUTED ALARM SYSTEM that is providing auditory ALARM SIGNALS, the volume of auditory ALARM SIGNALS shall generate a sound-pressure level of at least 45 dBA at 1 m, and shall not be adjustable by the OPERATOR without the use of a TOOL below 45 dBA at 1 m.

For INFUSION PUMPS FOR AMBULATORY USE, the volume of auditory ALARM SIGNALS shall generate a sound-pressure level of at least 45 dBA at 1 m, and shall not be adjustable without either the use of a TOOL or by special means by the OPERATOR.

EXAMPLE Special means consisting of pressing a sequence of keys.

Compliance is checked by inspection and functional testing. Utilize the test method specified in IEC 60601-1-8:2006, 6.3.3.2, to measure the sound-pressure level.

208.6.3.3.2.102 * AUDIO PAUSED period

The duration of AUDIO PAUSED required by this standard shall not exceed 120 s without OPERATOR intervention.. This requirement does not apply to INFUSION PUMPS FOR AMBULATORY USE.

NOTE This permits an OPERATOR to extend deliberately the duration of AUDIO PAUSED by direct action.

FOR INFUSION PUMPS FOR AMBULATORY USE the maximum time for AUDIO PAUSED is specified according to the RISK ASSESSMENT of the MANUFACTURER

The AUDIO PAUSED shall be indicated visually during the AUDIO PAUSED period.

Compliance is checked by inspection and functional test.

Annexes

The annexes of the general standard apply, with the following exception:

Addition:

Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

ADMINISTRATION SETS are not fully tested by this particular standard, but it is recognized that INFUSION PUMPS and INFUSION 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 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.

AA.2 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclause in this particular standard, with clause and subclause numbers parallel to those in the body of the document.

Subclause 2.3.212 and 201.3.213 – MAXIMUM SELECTABLE RATE and MINIMUM SELECTABLE RATE

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, and adds new definitions of MAXIMUM SELECTABLE RATE and LOWEST 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.

Subclause 201.4.7 – SINGLE FAULT CONDITION for ME EQUIPMENT

In order to protect the PATIENT from a HAZARD due to failure of the protective systems specified in subclause 201.12.4, subclause 201.4.7 of this standard requires that SINGLE FAULT CONDITIONS occurring in these protective systems become obvious to the OPERATOR while the equipment is operational.

One method of implementing this would be for the ME EQUIPMENT to continuously carry out self-check routines and alarm and stop infusing if a SINGLE FAULT CONDITION occurs (see example 1 of 201.4.7). 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 3 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.

The following items are regarded as NORMAL CONDITION:

- leakage from the ADMINISTRATION SET and/or the liquid supply;
- depletion of the INTERNAL ELECTRICAL POWER SOURCE;
- mispositioning and/or incorrect filling of a drop chamber;
- air in the SUPPLY LINE or that part of the ME EQUIPMENT within which flow regulation, flow shut-off or air detection occurs;

– pulling on the PATIENT LINE (see ISO 8536-4);
– because this will happen during usual infusion therapy.

Subclause 201.7.9.2.101 – Instruction for use

201.7.9.2.101, 4th item (instruction and references)

The instructions can include references to ADMINISTRATION SET instruction for use.

201.7.9.2.101, 14th item

Due to the power consumption of VOLUMETRIC INFUSION PUMPS or VOLUMETRIC INFUSION CONTROLLERS the operating time may vary between different set rates. This information is useful for the OPERATOR of the equipment during transport conditions.

201.7.9.2.101, 17th item

Examples of conditions under which the ME 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 ME EQUIPMENT. The MANUFACTURER should specify the parameters in which the device cannot maintain the specified accuracy; e.g., viscosity of liquids, back pressure, infusion rates, reaction time of the safety system, scope of the risk analysis, etc.

Subclause 201.7.9.2.101, 18th item

Examples of a 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.

Subclause 201.7.9.2.101, 23rd item

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 ME EQUIPMENT stops.

Subclause 201.7.9.2.101, 29th item

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

Subclause 201.7.9.3.101, 1st item

For INFUSION PUMPS FOR AMBULATORY USE using insulin there is no direct HAZARD associated with infusion of air. Infusion of air bubbles compromises dosing accuracy when insulin is substituted by air causing an underinfusion that however is commonly detected/prevented by e.g. blood glucose measurement, visual inspection of infusion sets and priming. Therefore it is not required (see 201.12.4.4.107) to have an air detector in an insulin pump. If however an air detector is provided, the MANUFACTURER may disclose in the technical description the sensitivity of the air detector in terms relevant for the design. This could be done by e.g. disclosing the possible amount of underinfusion until the air detector is triggered or a similar description.

Subclause 201.11.6.3 – Spillage on ME EQUIPMENT and ME SYSTEMS

If any liquid ingress occurs in the test, even if there is no sign of wetting of parts that could result in a HAZARDOUS SITUATION, consideration should be given to the possibility that similar liquid ingress on another occasion might reach other parts where it could cause incorrect performance such as over- or underinfusion.

Subclause 201.12.1 – Accuracy of controls and instruments

201.12.1.101 General formula

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

Accuracy of these ME EQUIPMENT may be affected by extremes of back pressure.

Subclause 201.12.1.102 – Accuracy tests for VOLUMETRIC INFUSION CONTROLLERS, VOLUMETRIC INFUSION PUMPS and SYRINGE OR CONTAINER PUMPS

to

Subclause 201.12.1.107 – Accuracy tests for INFUSION PUMP type 5

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 ME EQUIPMENT to suit the clinical application. Graphs of the type shown in Figures 201.105 and 201.110 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 201.12.1.102 to 201.12.1.104, 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 lead screw is engaged (for SYRINGE OR CONTAINER PUMPS);

d) set delivery rate;

e) compliances within the syringe/container.

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 ME EQUIPMENT. Tests for this are conducted as described in 201.12.1.102 to 201.12.1.104 ((see 201.12.1)) and example graphs are shown in Figures 201.106, 201.107 and 201.109.

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 ME 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 ME EQUIPMENT: rotary and linear peristaltic, diaphragm and piston types, and even SYRINGE OR CONTAINER PUMPS. With certain ME 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 ME 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.

VOLUMETRIC INFUSION CONTROLLERS (drop controlled) 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_2 = 8,83 kPa) is greater than the maximum venous pressure likely to be encountered in clinical practice (approximately 2,67 kPa (20 mmHG)).

The maximum drop 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 18G, 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 mmHG). With higher viscosity liquids, such as dextrose (50 %), these figures increase to 0,43 kPa (3,2 mmHG) (with an 18G, 1,2 mm needle 40 mm long) and 2,86 kPa (21,4 mmHG) (with a 21G, 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 ME EQUIPMENT.

VOLUMETRIC INFUSION CONTROLLERS use gravity to supply the required infusion pressure. However, these VOLUMETRIC INFUSION CONTROLLERS 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 drop 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 drop rate, temperature, pressure, the material 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 3696:1987 class III 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.

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 VOLUMETRIC INFUSION PUMPS for accuracy of delivery below 1 ml/h because clinical applications would call for the use of a SYRINGE OR CONTAINER PUMP in these circumstances.

These ME EQUIPMENT are tested over the intermediate rate 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.

Subclause 201.12.4.4.102 – Protection against overinfusion FREE FLOW conditions

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.

Subclause 201.12.4.4.107 – Protection against air infusion

SYRINGE OR CONTAINER PUMPS, INFUSION PUMPS FOR AMBULATORY USE and ENTERAL NUTRITION PUMPS are excluded from the requirement of an air detector because no vented containers can be used. The syringes or containers are prefilled, filled-up by the operator. In some cases "air bubbles" can be seen in the container, but these bubbles come from dissolved air from the liquid. With regard to the connection point to the patient (e.g. venous) these little "air bubbles" have no influence to the patient. For ENTERAL NUTRITION PUMPS no unacceptable RISK occurs, because the enteral nutrition will be pump into the stomach.

Subclause 201.13.2.6 – Leakage of liquid

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

Subclause 201.15.103 – Use errors

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 auditory 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.

SYRINGE OR CONTAINER PUMPS and INFUSION PUMPS FOR AMBULATORY USE are excluded because the pump level is equal or below the level of the PATIENT. Also the friction of the syringe/container may prevent free flow conditions.

Subclause 208.6.3.3.1 – Characteristics of auditory ALARM SIGNALS

For INFUSION PUMPS FOR AMBULATORY use it is difficult to comply with the frequency and harmonics requirement of the IEC 60601-1-8:2006 because of the technique is used for the audible alarm source maybe piezoelectric for power consumption and ingress of water (e.g. IPXX classification). These types of pumps are generally not used in the hospital environment.

If OPERATORS are familiar with the auditory ALARM SIGNALS of existing INFUSION PUMPS or VOLUMETRC INFUSION CONTROLLERS which are not in accordance with IEC 60601-1-8, it may be better to retain similar auditory ALARM SIGNALS in new devices, subject to a RISK assessment by the RESPONSIBLE ORGANIZATION.

Subclause 208.6.3.3.2.102 – AUDIO PAUSED period

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

AA.3 Rationale for the algorithm for this particular standard

Accuracy tests for PUMPS FOR AMBULATORY USE

INFUSION PUMPS 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 INFUSION 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 with a period of 2 h has no observable clinical disadvantage. Even at this low shot frequency, delivery may be defined as quasi-continuous.

For luteinising 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 is 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 four subgroups on the basis of the mode of delivery:

- type 1: continuous infusion;
- type 2: non-continuous flow only;
- type 3: discrete delivery of a bolus;
- type 4: PROFILE PUMP.

Flow errors

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.101) 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".

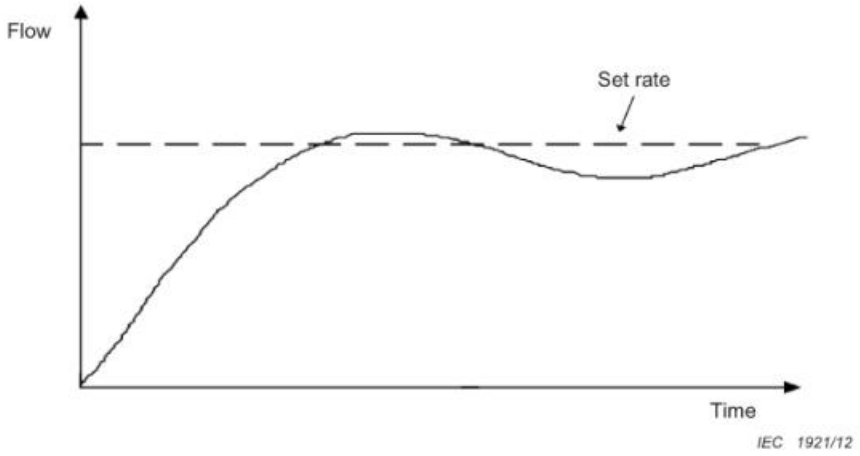


Figure AA.101 – Start-up graph

After stabilization, data are 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.102). 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.

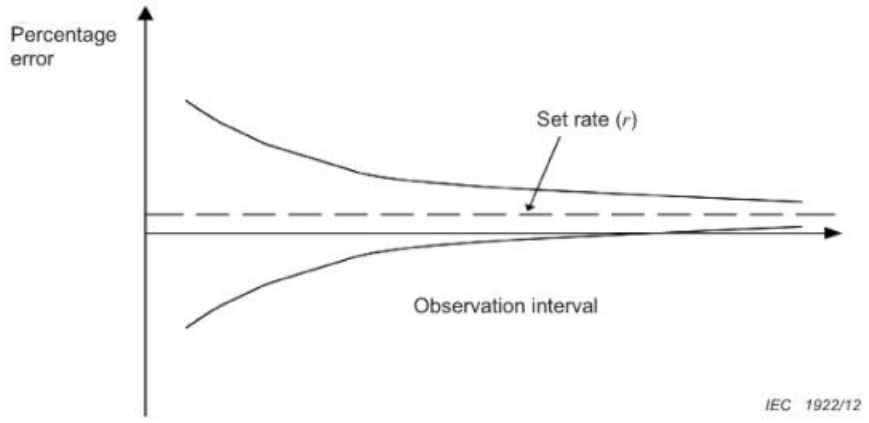


Figure AA.102 – Trumpet curve

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 201.12.1.102 to 201.12.1.107).

It may be necessary to produce different scales of percentage variation in flow or drop rate depending on the type of ME 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 kth 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;

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

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.103 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 ith mass sample of the analysis period T, not the ith mass sample of the test period. Any e_i is calculated from the following equation;

$$Q_i = \frac{60\,(W_i - W_{i-1})}{Sd} \qquad \text{(AA.2)}$$

$$e_i = 100\,(Q_i - r)/r \qquad \text{(AA.3)}$$

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.103.

This calculation is repeated for all m observation windows determined from Equation AA.1. Equation AA.7 calculates the mean flow error E_p for all observation windows of duration P.

For the first window

$$E_p(1) = \frac{e_1 + e_2 + \ldots + e_{P/S}}{P/S} \qquad \text{(AA.4)}$$

For the second window

$$E_{\mathrm{p}}(1) = \frac{e_2 + \ldots + e_{P/S+1}}{P/S} \tag{AA.5}$$

For the m^{th} window

$$E_{\mathrm{p}}(1) = \frac{e_{\mathrm{m}} + e_{\mathrm{m}+1} + \ldots + e_{P/S} + e_{P/S+\mathrm{m}-1}}{P/S} \tag{AA.6}$$

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

$$E_{\mathrm{p}}(\mathrm{j}) = \frac{S}{P} \times \sum_{\mathrm{i}=\mathrm{j}}^{\mathrm{j}+\frac{P}{S}-1} e_{\mathrm{i}} \tag{AA.7}$$

The final calculation stage is to determine the maximum $E_{\mathrm{p}}(\mathrm{max.})$ and minimum $E_{\mathrm{p}}(\mathrm{min.})$ percentage variations within the observation window of duration P. These parameters are simply the maxima of the $E_{\mathrm{p}}(\mathrm{j})$ calculated from Equation AA.7. Hence:

For the maximum

$$E_{\mathrm{p}}(\mathrm{max.}) = \text{Maximum } (E_{\mathrm{p}}(1), E_{\mathrm{p}}(2), .., E_{\mathrm{p}}(\mathrm{m})) \tag{AA.8}$$

or

$$E_{\mathrm{p}}(\mathrm{max.}) = \underset{\mathrm{j}=1}{\overset{\mathrm{m}}{\mathrm{MAX}}}\left(E_{\mathrm{p}}(\mathrm{j})\right) \tag{AA.9}$$

Similarly, for the minimum

$$E_{\mathrm{p}}(\mathrm{min.}) = \text{Minimum } (E_{\mathrm{p}}(1), E_{\mathrm{p}}(2), .., E_{\mathrm{p}}(\mathrm{m})) \tag{AA.10}$$

or

$$E_{\mathrm{p}}(\mathrm{min.}) = \underset{\mathrm{j}=1}{\overset{\mathrm{m}}{\mathrm{MIN}}}\left(E_{\mathrm{p}}(\mathrm{j})\right) \tag{AA.11}$$

All four calculation stages may be combined into a single Equation for $E_{\mathrm{p}}(\mathrm{max.})$ and $E_{\mathrm{p}}(\mathrm{min.})$ respectively:

$$E_{\mathrm{p}}(\mathrm{max.}) = \underset{\mathrm{j}=1}{\overset{\mathrm{m}}{\mathrm{MAX}}}\left[\frac{S}{P} \times \sum_{\mathrm{i}=\mathrm{j}}^{\mathrm{j}+\frac{P}{S}-1} 100 \times \left(\frac{Q_{\mathrm{i}} - r}{r}\right)\right] \tag{AA.12}$$

$$E_{\mathrm{p}}(\mathrm{min.}) = \underset{\mathrm{j}=1}{\overset{\mathrm{m}}{\mathrm{MIN}}}\left[\frac{S}{P} \times \sum_{\mathrm{i}=\mathrm{j}}^{\mathrm{j}+\frac{P}{S}-1} 100 \times \left(\frac{Q_{\mathrm{i}} - r}{r}\right)\right] \tag{AA.13}$$

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.1 to AA.13 should be recalculated for each new value of P = 1, 2, 5, 11, 19 and 31 min.

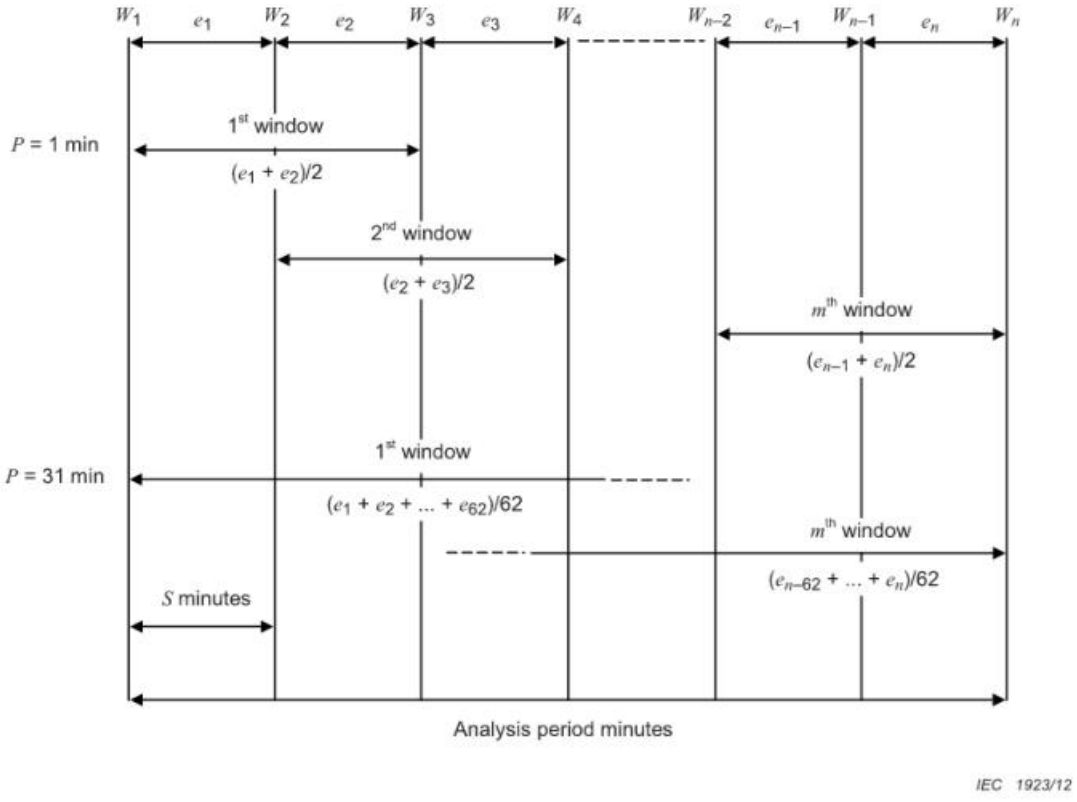


Figure AA.103 – Calculation for E_p(max.) and E_p(min.)

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

This rationale is not direct linked to the normative requirements if this standard. However for further investigations for the next amendment of IEC 60601-2-24 and to reflect daily use of an infusion technology it is a combination between different infusion pumps of the same model and different administration sets of the same brand. Therefore it is interesting to know what the overall variability of the accuracy is. This will help the medical staff for the medical treatment.

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. Firstly, it should identify the variation in the mean flow over a specific measurement interval. Secondly, it should be able to produce data that is both reliable and reproducible. Both 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 of the long-term flow is also characterized by these statistics of mean flow and variance.

By determining the probability density function 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 probability density function of individual samples can be determined from the long-term flow statistics, a method is required to determine the probability density function 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.104, 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.

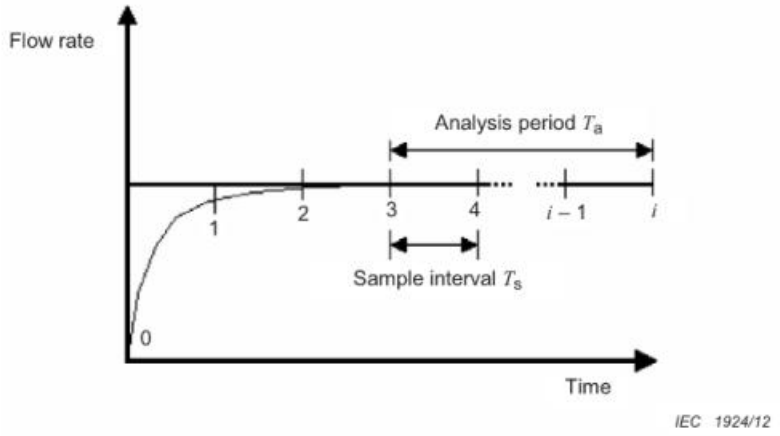


Figure AA.104 – Sampling protocol

With reference to Figure AA.105, 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.

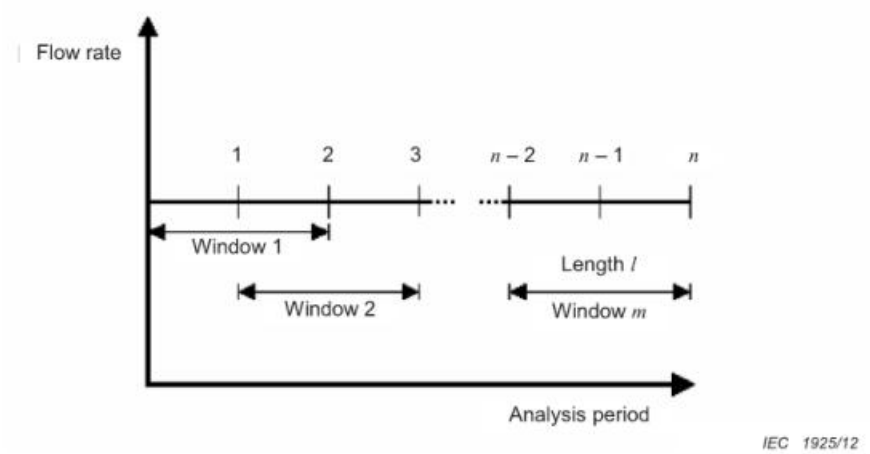


Figure AA.105 – Observation windows

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, 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 $$x = \frac{1}{n} \times \sum_{i=1}^{n} X_i \qquad \text{(AA.4.1)}$$

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

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.106).

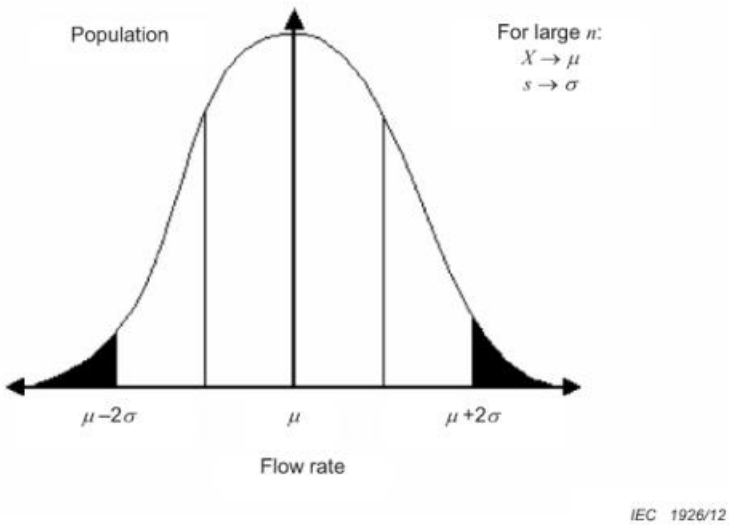


Figure AA.106 – Distribution of parent variate X

The probability distribution of the parent population defines the probability distribution of individual samples. The probability density function 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 probability density function of each observation window may be determined.

Observation window	Mean	Standard deviation
1 min	μ	$\sigma \times \sqrt{T_s}$
2 min	μ	$\sigma \times \sqrt{T_s / 2}$
l min	μ	$\sigma \times \sqrt{T_s / l}$

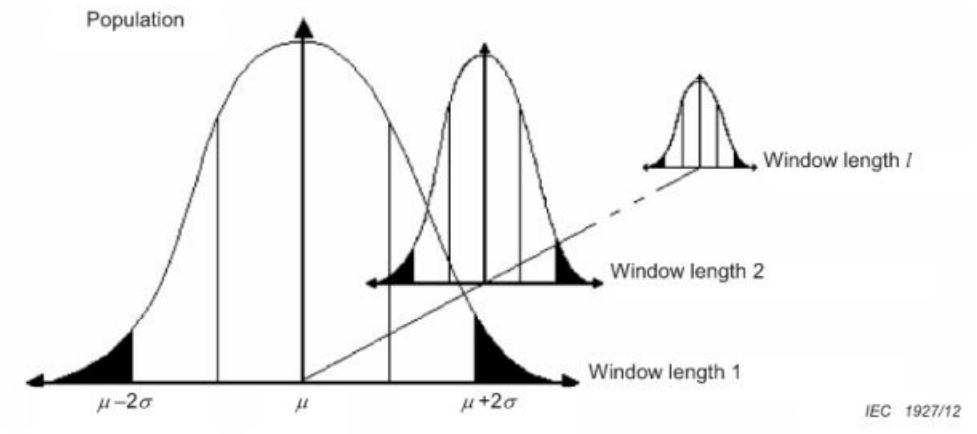


Figure AA.107 – Distribution of observation windows

Each probability density function 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.

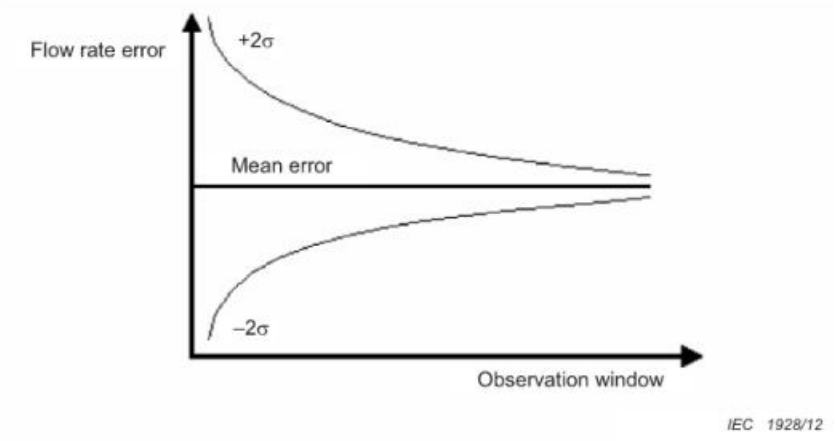


Figure AA.108 – The statistical trumpet graph

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 probability density function 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 probability density function 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 OR CONTAINER 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 $\pm 3\sigma$ limits from one INFUSION PUMP. The study concluded that 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.

Bibliography

IEC 61000-4-2, *Electromagnetic compatibility (EMC) – Part 4-2: Testing and measurement techniques – Electrostatic discharge immunity test*

Index of defined terms used in this particular standard