

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –

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

Appareils électromédicaux –

Partie 2-24: Exigences particulières pour la sécurité de base et les performances essentielles des pompes et régulateurs de perfusion



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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

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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 standard¹ 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.

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 SYRINGE 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 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
$E_p(\text{max.})$	maximum measured error in observation window of specified duration
$E_p(\text{min.})$	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 $\pm 13,33$ 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 $E_p(\text{max.})$ and $E_p(\text{min.})$ 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 $E_p(\text{max.})$ and $E_p(\text{min.})$ 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 $E_p(\text{max.})$ and $E_p(\text{min.})$ 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:

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

$i = 1, 2 \dots T_0/S$

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 $E_p(\text{max.})$ and $E_p(\text{min.})$ 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:

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

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 $E_p(\text{max.})$ and minimum $E_p(\text{min.})$ percentage variations within an observation window of duration period P min are given by:

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

$$E_p(\text{min.}) = \text{MIN}_{j=1}^m \left[\frac{S}{P} \times \sum_{i=j}^{j+\frac{P}{S}-1} 100 \times \left(\frac{Q_i - r}{r} \right) \right] (\%) \quad (4)$$

where

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

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

r is the rate (ml/h);

S is the sample interval (min);

P is the observation window duration (min);

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

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

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

where

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

r is the rate (ml/h);

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

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

T_1 is the analysis period (min);

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

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

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

where

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

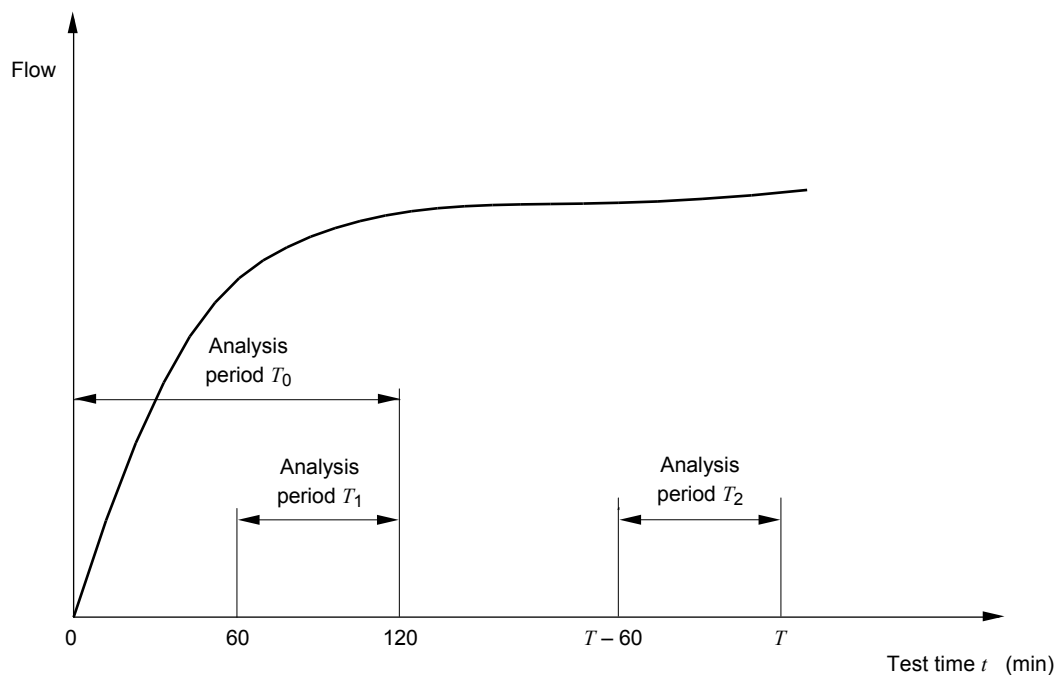
r is the rate (ml/h);

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

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

T_2 is the analysis period (min);

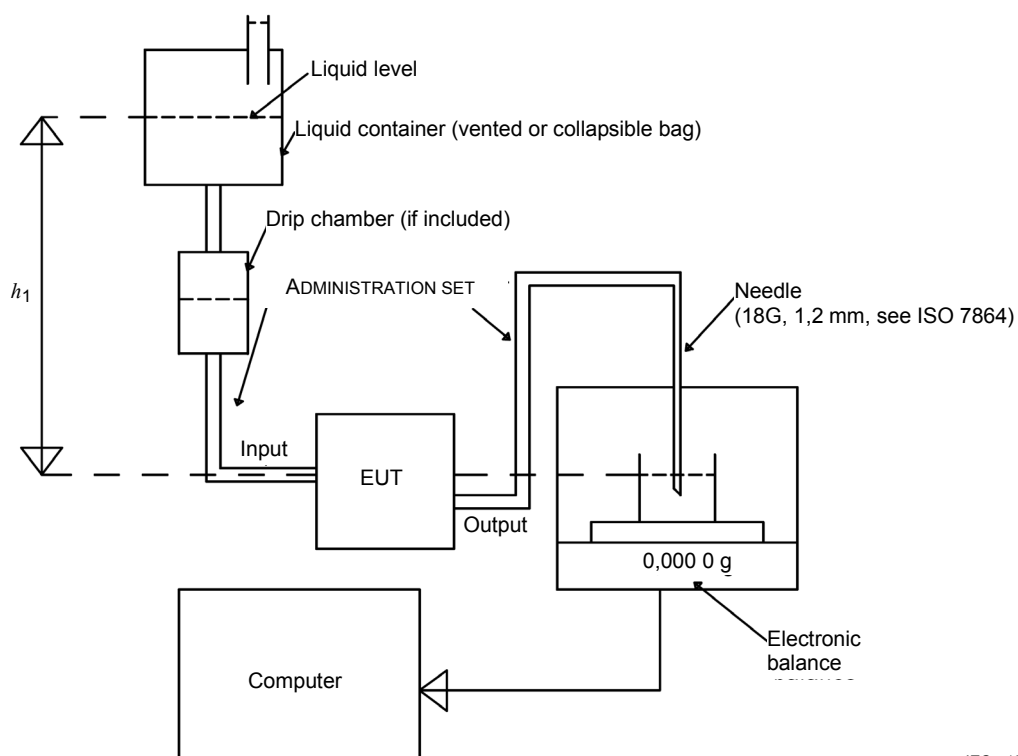
d is the density of water (0,998 g/ml at 20 °C).



T = ADMINISTRATION SET CHANGE INTERVAL

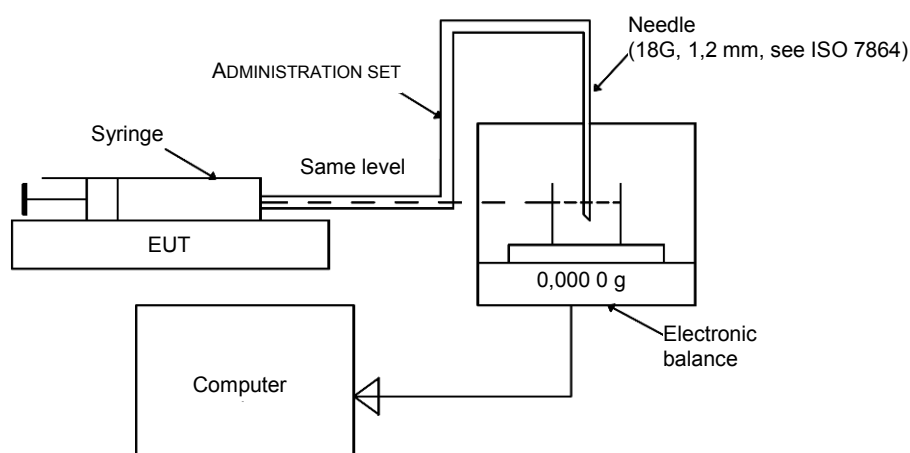
IEC 1910/12

Figure 201.103 – Analysis periods



IEC 1911/12

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



IEC 1912/12

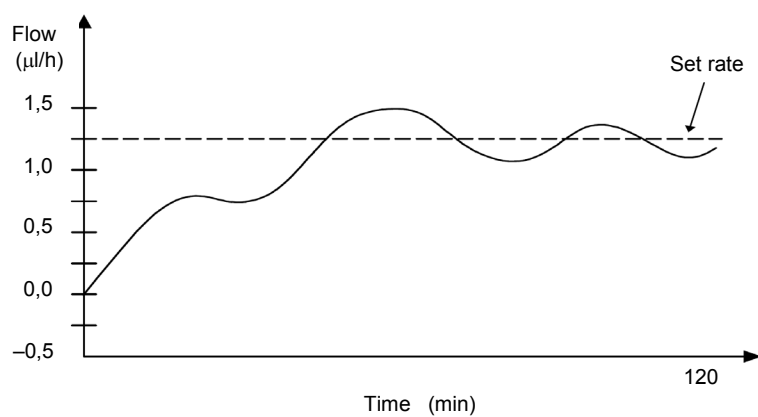
Figure 201.104b – Test apparatus for SYRINGE OR CONTAINER PUMPS

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.

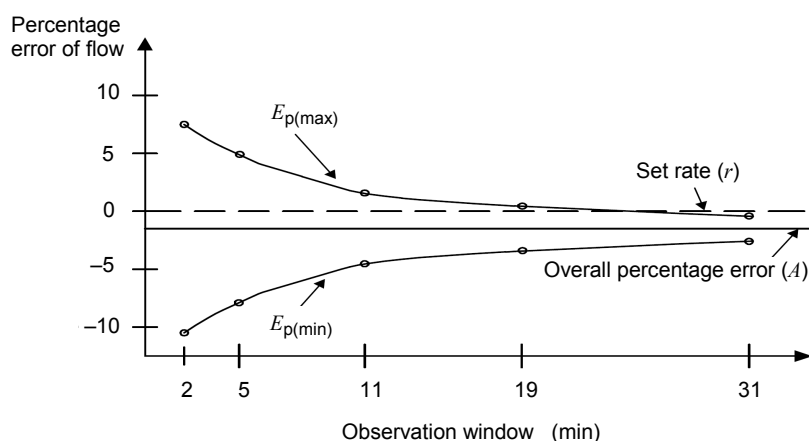
The mean centre line of the pumping chamber to be at the same height as the tip of the needle (18G, 1,2 mm, ISO 7864).

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

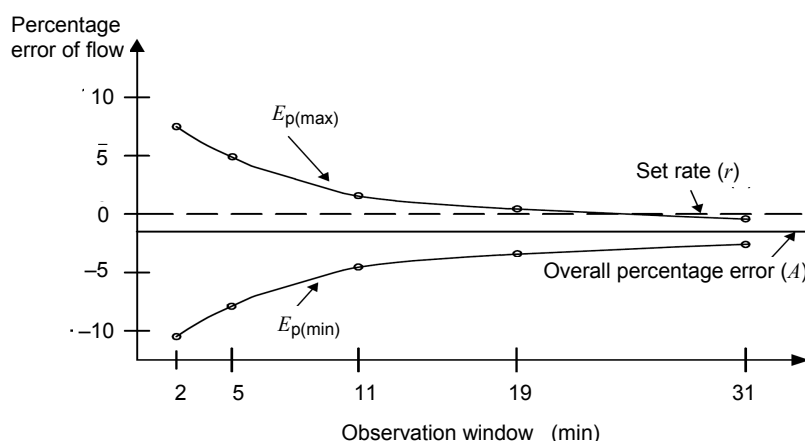
IEC 1913/12

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



IEC 1914/12

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



IEC 1915/12

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 $E_p(\text{max.})$ and $E_p(\text{min.})$ 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:

- Flow Q_i ($\mu\text{l/h}$) against time (min) over the stabilization period T_1 at 30 min increments. Indicate the rate r ($\mu\text{l/h}$) by means of a broken line. Indicate flow Q_i by means of a solid line. See Figure 201.108 as an example.
- Percentage variation $E_p(\text{max.})$ and $E_p(\text{min.})$ 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 $E_p(\text{max.})$ and $E_p(\text{min.})$ and the overall mean percentage error A by means of solid lines. See Figure 201.109 as an example.

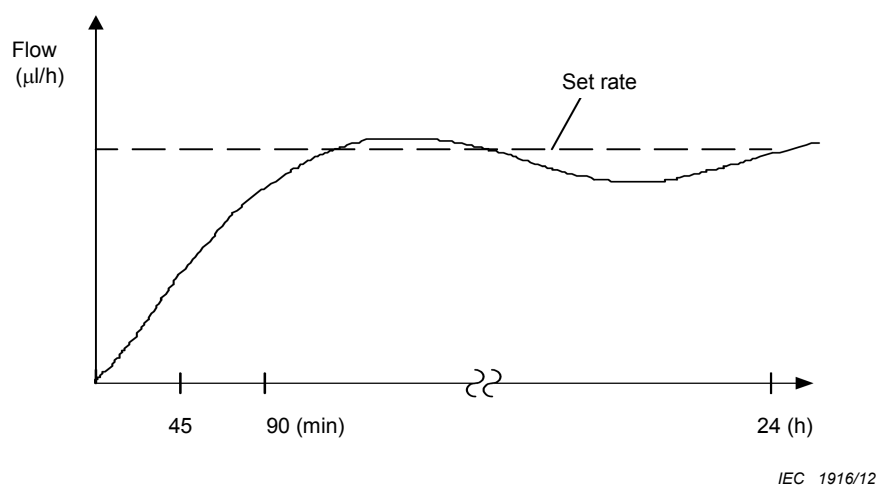


Figure 201.108 – Start-up graph over the stabilization period

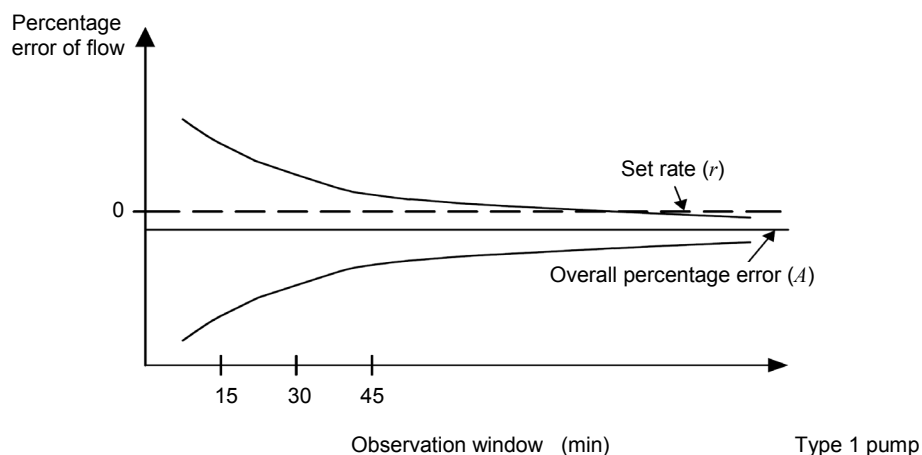
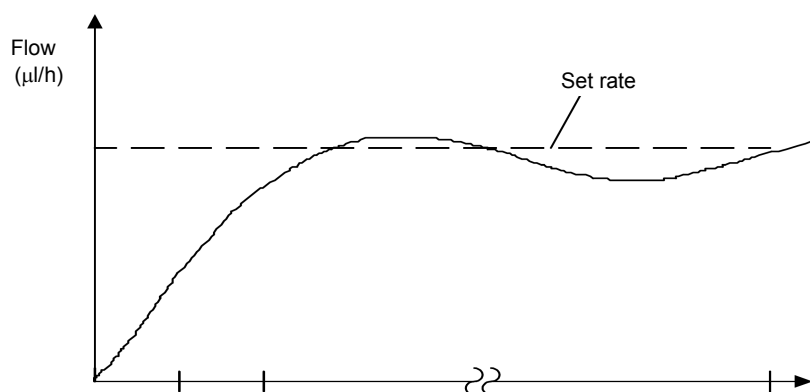
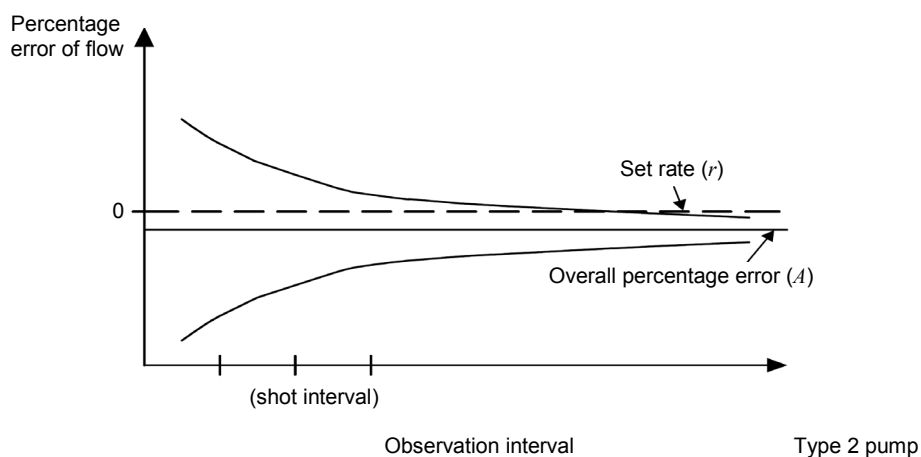


Figure 201.109 – Trumpet curve plotted from data at the end of the stabilization period



IEC 1918/12

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



IEC 1919/12

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:

$$Q_i = \frac{60 (W_{2i} - W_{2(i-1)})}{2dS} (\mu\text{l/h}) \quad (13)$$

where

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

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

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

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

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

Calculate $E_p(\text{max.})$ and $E_p(\text{min.})$ using the trumpet algorithm as follows:

For observation windows of duration $P = 15 \text{ min}$, 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:

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

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 $E_p(\text{max.})$ and minimum $E_p(\text{min.})$ percentage variations, within an observation window of duration period P (min), are given by;

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

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

where

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

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

r is the set rate ($\mu\text{l/h}$);

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 :

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

where

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

- r is the set rate ($\mu\text{l/h}$);
- 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:

$$S = kI \quad (18)$$

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

$$S = kI \quad (19)$$

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:

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

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 $E_p(\text{max.})$ and $E_p(\text{min.})$ 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 $E_p(\text{max.})$ and $E_p(\text{min.})$ 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 $E_p(\text{max.})$ and $E_p(\text{min.})$ 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:

$$Q_i = \frac{60 (W_{ni} - W_{n(i-1)})}{ndS} (\mu\text{l/h}) \quad (21)$$

where

$i = 1, 2.. T_1/nS$;

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

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

S is the sample interval (min) = (k/min);

n is the integer constant ($nS \approx 30$ min);

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

Calculate $E_p(\text{max.})$ and $E_p(\text{min.})$ 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:

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

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 $E_p(\text{max.})$ and minimum $E_p(\text{min.})$ percentage variations, within an observation window of duration period P (min), are given by:

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

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

where

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

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

r is the set rate ($\mu\text{l/h}$);

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

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

r is the set rate ($\mu\text{l/h}$);

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 INFUSION PUMPS FOR AMBULATORY USE type 4 where a continuous or quasi-continuous flow is maintained throughout the BOLUS delivery. These factors are disclosed in the ACCOMPANYING DOCUMENTS.

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).

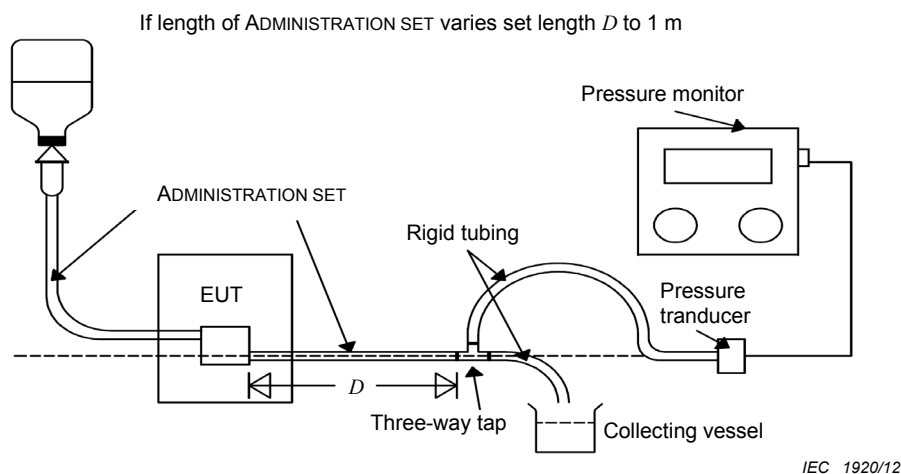


Figure 201.112 – Test apparatus to determine the OCCLUSION ALARM THRESHOLD and BOLUS volumes

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