



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 (ED. 2.0), MOD)



AS 60601.2.24:2018

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- Australasian College of Physical Scientists and Engineers in Medicine
- Australian and New Zealand College of Anaesthetists
- Australian Chamber of Commerce and Industry
- Australian College of Perioperative Nurses
- Australian Radiation Protection and Nuclear Safety Agency
- Australian Society of Anaesthetists
- Certification Body Australia (Certification Interests Australia)
- College of Biomedical Engineering, Engineers Australia
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Part 2.24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers (IEC 60601-2-24:2012 (ED. 2.0), MOD)

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Preface

This Standard was prepared by the Australian members of the Joint Standards Australia/Standards New Zealand Committee HE-003, Medical Electrical Equipment, to supersede AS/NZS 3200.2.24:1999, *Particular requirements for safety — Infusion pumps and controllers (IEC 60601-2-24:1998, MOD)*.

After consultation with stakeholders in both countries, Standards Australia and Standards New Zealand decided to develop this Standard as an Australian Standard rather than an Australian/New Zealand Standard.

The objective of this Standard is to specify basic safety and essential performance requirements for infusion pumps, infusion pumps for ambulatory use, syringe or container pumps, volumetric infusion controllers and volumetric infusion pumps. The minimum specified safety requirements provide a practical degree of safety to assist operators using the equipment.

This Standard amends and supplements the general Standard IEC 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*.

This Standard is an adoption with national modifications, and has been reproduced from, IEC 60601-2-24:2012 (ED. 2.0), *Medical electrical equipment — Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers*. [Appendix ZZ](#) lists the variations for the application of this Standard in Australia.

As this document has been reproduced from an International Standard, the following applies:

- (a) In the source text “this particular Standard” should read “this Australian Standard”.
- (b) A full point substitutes for a comma when referring to a decimal marker.

Australian or Australian/New Zealand Standards that are identical adoptions of international normative references may be used interchangeably. Refer to the online catalogue for information on specific Standards.

The terms “normative” and “informative” are used in Standards to define the application of the appendices to which they apply. A “normative” appendix is an integral part of a Standard, whereas an “informative” appendix is only for information and guidance.

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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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- 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 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