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Edition 2.0 2012-10

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

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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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IEC 60601-2-24:2012

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

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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

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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.

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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.

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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.

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MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 Scope, object and related standards

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

201.1.1 Scope

Replacement:

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

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

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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.

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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:

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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.

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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*

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

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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*

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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

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

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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

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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.

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Table 201.101 – Distributed ESSENTIAL PERFORMANCE requirements

IEC 60601-2-24:2012
https://standards.iteh.ai/catalog/standards/sist/160d87f4-23dd-41e7-ba01-
aa5f455f1e8f/iec-60601-2-24-2012

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

201.4.7 * SINGLE FAULT CONDITION for ME EQUIPMENT

Addition:

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

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

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

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

3) a safety system check carried out by the OPERATOR at least once within the ADMINISTRATION SET CHANGE INTERVAL (see the 21st dashed item of 201.7.9.2.101).

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

– leakage from the ADMINISTRATION SET and/or the liquid supply;
– depletion of the INTERNAL ELECTRICAL POWER SOURCE;
– mispositioning and/or incorrect filling of a drop chamber;
– air in the SUPPLY LINE or that part of the ME EQUIPMENT within which flow regulation, flow shut-off or air detection occurs;
– pulling on the PATIENT LINE (see ISO 8536-4).

201.5 General requirements for testing of ME EQUIPMENT

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

201.5.2 Number of samples

Addition:

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

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Compliance is checked by review of the technical documentation

IEC 60601-2-24:2012
https://standards.iteh.ai/catalog/standards/sist/1600d87f-25dd-41e7-ba01-aea5145f51e8/iec-60601-2-24-2012

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: