INTERNATIONAL STANDARD

IEC 60601-2-24

First edition
1998-02

Medical electrical equipment –

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

Appareils électromédicaux –

Partie 2-24:
Règles particulières de sécurité des pompes et régulateurs de perfusion

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
2) The formal decisions or agreements of the IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.
3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical reports or guides and they are accepted by the National Committees in that sense.
4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.
5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.
6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

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

The text of this Particular Standard is based on the following documents:

FDIS	Report on voting
62D/250/FDIS	62D/268/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.

Annex L is an integral part of this standard.

Annex AA is for information only.

In this Particular Standard the following print types are used:

– requirements, compliance with which can be tested, and definitions: in roman type;
– notes, explanations, advice, introductions, general statements, exceptions and references: in smaller type;
– *test specifications: in italic type;*
– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD IEC 60601-1 OR THIS PARTICULAR STANDARD: SMALL CAPITALS.

A bilingual version of this standard may be issued at a later date.

INTRODUCTION

This Particular Standard deals with the safety of INFUSION PUMPS and CONTROLLERS. The relationship between this Particular Standard, IEC 60601-1 (including amendments 1 and 2), 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 EQUIPMENT can only be achieved if it is operated in accordance with the manufacturer's instructions for use. The minimum specified safety requirements are considered to provide a practical degree of safety in operation. It is the responsibility of the manufacturer to ensure that the requirements of this Particular Standard are reliably implemented. This Particular Standard has been developed in accordance with these principles.

Safe use can be ensured only if the associated disposable parts, especially lines and syringes are consistent with the system. ISO 7886-2:1996, *Sterile hypodermic syringes for single use – Part 2: Syringes for use with power-driven syringe pumps* should be taken into account.

MEDICAL ELECTRICAL EQUIPMENT –

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

SECTION ONE – GENERAL

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

1 Scope and object

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

1.1* Scope

Addition:

This Particular Standard specifies the requirement for INFUSION PUMPS, INFUSION CONTROLLERS, SYRINGE PUMPS and PUMPS FOR AMBULATORY USE, as defined in 2.101 to 2.110. These devices are intended for use by medical staff and home PATIENTS as prescribed and medically indicated. These particular requirements do not apply to devices:

1) specifically intended for diagnostic or similar use (e.g. angiography or other pumps permanently controlled or supervised by the OPERATOR),
2) enteral infusion,
3) extracorporeal circulation of blood,
4) implantable or disposable devices,
5) EQUIPMENT specifically intended for diagnostic use within urodynamics (measurement of pressure-volume relationship of the urinary bladder when filled through a catheter with water);
6) EQUIPMENT specifically intended for diagnostic use within male impotence testing (measurement of amount of liquid infused, necessary to maintain a preset pressure level for maintaining penile erection: cavernosometry, cavernosography).

1.3 Particular standards

Addition:

This Particular Standard refers to IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety* as amended by its amendment 1 (1991) and amendment 2 (1995) and to the Collateral Standard IEC 60601-1-2:1993, *Medical electrical equipment – Part 1: General requirements for safety – 2. Collateral Standard: Electromagnetic compatibility – Requirements and tests.*

For brevity, Part 1 is referred to in this Particular Standard either as the General Standard or as the General Requirement(s) and IEC 60601-1-2 as the Collateral Standard.

The numbering of sections, clauses and subclauses of this Particular Standard corresponds to that of the General Standard. The changes to the text of the General Standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the General Standard is replaced completely by the text of this Particular Standard.

"Addition" means that the text of this Particular Standard is additional to the requirements of the General Standard.

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

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

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

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

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

The requirements are followed by specifications for the relevant tests.

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

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

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

1.5 Collateral Standards

Addition:

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

2 Terminology and definitions

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

2.1.3
ACCESSORY

Addition:

Separate programmers are regarded as accessories and therefore a component part of the EQUIPMENT

2.1.5
APPLIED PART

Replacement:

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

2.2.18
PORTABLE EQUIPMENT

Replacement:

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

Additional definitions:

2.101
INFUSION PUMP
EQUIPMENT intended to regulate the flow of liquids into the PATIENT under positive pressure generated by the pump

The INFUSION PUMP may be of:

– type 1: continuous infusion flow only,
– type 2: non-continuous flow only,
– type 3: discrete delivery of a BOLUS,
– type 4: type 1 combined with type 3 and/or type 2 in the same EQUIPMENT,
– type 5: PROFILE PUMP.

2.102
VOLUMETRIC INFUSION PUMP
INFUSION PUMP in which the delivery rate is set by the OPERATOR and indicated by the EQUIPMENT in volume per unit of time, but excluding SYRINGE PUMPS

2.103
DRIP-RATE INFUSION PUMP
INFUSION PUMP in which the delivery rate is set by the OPERATOR and indicated by the EQUIPMENT as a number of drops per unit of time

2.104
INFUSION CONTROLLER
EQUIPMENT intended to regulate the flow of liquid into the PATIENT under positive pressure generated by gravitational force

2.105
VOLUMETRIC INFUSION CONTROLLER
INFUSION CONTROLLER in which the delivery rate is set by the OPERATOR and indicated by the EQUIPMENT in volume per unit of time

2.106
DRIP-RATE INFUSION CONTROLLER
INFUSION CONTROLLER in which the delivery rate is set by the OPERATOR and indicated by the EQUIPMENT as a number of drops per unit of time

2.107
SPECIAL USE EQUIPMENT
EQUIPMENT in which the delivery rate is set by the OPERATOR and indicated by the EQUIPMENT in units other than those defined in 2.101 to 2.106

2.108
SYRINGE PUMP
EQUIPMENT intended for controlled infusion of liquids into the PATIENT by means of one or more single action syringe(s) or similar container(s) (e.g. where the cartridge is emptied by pushing on its plunger)) and in which the delivery rate is set by the OPERATOR and indicated by the EQUIPMENT in volume per unit of time

2.109
INFUSION PUMP FOR AMBULATORY USE
EQUIPMENT intended for the controlled infusion of liquids into the PATIENT and intended to be carried continuously by the PATIENT

2.110
PROFILE PUMP
EQUIPMENT intended for controlled infusion of liquids into the PATIENT by means of a programmed sequence of delivery rates

2.111
REGION OF CONTROL
that part of the EQUIPMENT within which flow regulation, flow shut-off or air detection occurs, within the body of the EQUIPMENT or remotely

2.112
ADMINISTRATION SET
device(s) that convey(s) liquid from the supply via the EQUIPMENT to the PATIENT

2.113
PATIENT LINE
that part of the ADMINISTRATION SET between the EQUIPMENT and the PATIENT

2.114
SUPPLY LINE
that part of the ADMINISTRATION SET between the liquid supply and the EQUIPMENT

2.115
OCCLUSION ALARM THRESHOLD (PRESSURE)
value of the physical quantity at which the occlusion alarm is activated

2.116
KEEP OPEN RATE (KOR)
low predetermined rate(s) to which the EQUIPMENT reverts under specified conditions with the object of keeping the PATIENT LINE open

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

2.117
FREE FLOW
flow in an ADMINISTRATION SET which is not controlled by the EQUIPMENT, for example, due to the unintended effects of gravity by the removal of the ADMINISTRATION SET from the EQUIPMENT

2.118
ADMINISTRATION SET CHANGE INTERVAL
time recommended by the manufacturer of the EQUIPMENT for using the ADMINISTRATION SET

2.119
BOLUS
discrete quantity of liquid which is delivered in a short time

2.120
INTERMEDIATE RATE defined as follows:
– for volumetric infusion pumps and volumetric infusion controllers, set the rate to 25 ml/h;
– for drip-rate infusion pumps and drip-rate infusion controllers, set the rate to 20 drops/minute;
– for syringe pumps, set the rate to 5 ml/h;
– for special use equipment and infusion pumps for ambulatory use, set the rate specified by the manufacturer as typical for the equipment.

2.121
MINIMUM RATE
lowest rate selectable by the OPERATOR, but not less than 1 ml/h

NOTE – For INFUSION PUMPS FOR AMBULATORY USE it is the lowest selectable rate.

2.122
MAXIMUM INFUSION PRESSURE
maximum pressure which can be generated by the EQUIPMENT under conditions of total occlusion at the end of the PATIENT LINE

2.123
PATIENT END
that end of the PATIENT LINE where connection to the PATIENT takes place

3 General requirements

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

3.6* *Addition*

SINGLE FAULT CONDITIONS occurring in those protective systems specified in 51.5 and 51.102 shall become obvious to the OPERATOR within the ADMINISTRATION SET CHANGE INTERVAL. SINGLE FAULT CONDITIONS occurring in the protective system specified in clause 51.103 shall cause the cessation of delivery and the generation of an alarm within a time interval less than the volume of the ADMINISTRATION SET between the air detector and the venous cannula connected to it divided by the maximum flow rate of the pump.

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

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

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

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

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

– leakage from the ADMINISTRATION SET and/or the liquid supply;
– depletion of the INTERNAL ELECTRICAL POWER SOURCE;
– mispositioning and/or incorrect filling of a drip chamber;

– air in the SUPPLY LINE or the REGION OF CONTROL;
– pulling on the PATIENT LINE (see ISO 8536-4).

5 Classification

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

5.2 *Amendment*:

Delete TYPE B APPLIED PART;

5.6 *Amendment:*

Delete all except for CONTINUOUS OPERATION.

6 Identification, marking and documents

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

6.1 Marking on the outside of EQUIPMENT or EQUIPMENT parts

Addition:

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

Compliance is checked by inspection.

6.1 q) *Physiological effects*

Replacement:

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

1) symbol No. 14 of appendix D of the General Standard or a statement to refer the OPERATOR to the ACCOMPANYING DOCUMENTS;
2) an arrow or other appropriate symbol indicating the correct direction of flow if the ADMINISTRATION SET can be incorrectly loaded;
3) EQUIPMENT as defined in 2.103 and 2.106 shall additionally be marked as follows:

   "Caution: this equipment controls the drip rate not the volume delivered."

Additional items:

6.1.201 of the Collateral Standard, IEC 60601-1-2

Addition:

Compliance is checked by inspection.

6.8 ACCOMPANYING DOCUMENTS

6.8.2 Instructions for use

a) *Addition:*

The instructions for use shall also include the following:

1) a list of the recommended ADMINISTRATION SET(S) to be used;
2) a warning of the consequences of the use of unsuitable ADMINISTRATION SET(S);
3) a list of particular ACCESSORIES recommended by the manufacturer for use with the EQUIPMENT;
4) permitted EQUIPMENT orientation and methods and precautions concerning its mounting, for example, stability on a pole;
5) instructions regarding loading, priming, changing and reloading the ADMINISTRATION SET(S), and the ADMINISTRATION SET CHANGE INTERVAL to maintain the specified performance;
6) instructions regarding the use of clamps on an ADMINISTRATION SET, the avoidance of FREE FLOW conditions and the procedure to be followed when changing liquid containers;
7) where gravity is relevant to performance, the acceptable height range of the liquid container above the PATIENT's heart;
8) the means provided to protect the PATIENT from air infusion;
9) a statement of the MAXIMUM INFUSION PRESSURE generated and the OCCLUSION ALARM THRESHOLD (PRESSURE)(S) of the EQUIPMENT;
10) a statement of the maximum time for activation of the occlusion alarm when the EQUIPMENT is operating at the MINIMUM RATE and the INTERMEDIATE RATE and at the minimum and maximum selectable OCCLUSION ALARM THRESHOLD (PRESSURE)(S);
11) a statement of the BOLUS volume generated as a result of the EQUIPMENT operating at the INTERMEDIATE RATE and reaching the minimum and maximum OCCLUSION ALARM THRESHOLD (PRESSURE) (see also 51.5 b));
12) a statement of the means provided (if any) to manage the BOLUS before occlusion release;
13) a statement to indicate to the OPERATOR if the EQUIPMENT cannot be used as PORTABLE EQUIPMENT;
14) precautions required with drop detectors, for example with respect to placement, cleanliness, liquid level, ambient light;
15) recommendations on any specific method of cleaning and maintaining the EQUIPMENT;
16) the typical operating time when the EQUIPMENT is operating from the INTERNAL ELECTRICAL POWER SOURCE at the INTERMEDIATE RATE;
17) a statement of KEEP OPEN RATE(S), and when initiated;
18) a list of alarms and their operating conditions;
19)* a warning that under certain circumstances the specified accuracy may not be maintained.

NOTE – The manufacturer must specify the parameters in which the device cannot maintain the specified accuracy; e.g. minimum/maximum viscosity of liquids, reaction time of the safety system, scope of the risk analysis, etc.

20)* reference to a guide on the SAFETY HAZARDS associated with the interconnection of other infusion systems or ACCESSORIES to the PATIENT LINE;
21) the rate obtained when the prime/purge or BOLUS control is operated, and a statement of any alarm disabled;
22) a warning statement on the possible SAFETY HAZARDS associated with external radio-frequency interference (RFI) or electromagnetic radiation which may affect the safe operation of the EQUIPMENT. This statement should include examples of typical EQUIPMENT which may generate such radiation;
23) the selectable rate range and the increments of selection;
24) guidance on tests to permit the OPERATOR to check the correct functioning of alarm(s) and the operational safety of the EQUIPMENT;