

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



Reference number
IEC 60601-2-24:1998(E)

Numbering

As from 1 January 1997 all IEC publications are issued with a designation in the 60000 series.

Consolidated publications

Consolidated versions of some IEC publications including amendments are available. For example, edition numbers 1.0, 1.1 and 1.2 refer, respectively, to the base publication, the base publication incorporating amendment 1 and the base publication incorporating amendments 1 and 2.

Validity of this publication

The technical content of IEC publications is kept under constant review by the IEC, thus ensuring that the content reflects current technology.

Information relating to the date of the reconfirmation of the publication is available in the IEC catalogue.

Information on the revision work, the issue of revised editions and amendments may be obtained from IEC National Committees and from the following IEC sources:

- **IEC Bulletin**
- **IEC Yearbook**
On-line access*
- **Catalogue of IEC publications**
Published yearly with regular updates
(On-line access)*

Terminology, graphical and letter symbols

For general terminology, readers are referred to IEC 60050: *International Electrotechnical Vocabulary* (IEV).

For graphical symbols, and letter symbols and signs approved by the IEC for general use, readers are referred to publications IEC 60027: *Letter symbols to be used in electrical technology*, IEC 60417: *Graphical symbols for use on equipment. Index, survey and compilation of the single sheets* and IEC 60617: *Graphical symbols for diagrams*.

IEC publications prepared by the same technical committee

The attention of readers is drawn to the end pages of this publication which list the IEC publications issued by the technical committee which has prepared the present publication.

* See web site address on title page.

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*

© IEC 1998 Copyright - all rights reserved — Droits de reproduction réservés

Aucune partie de cette publication ne peut être reproduite ni utilisée sous quelque forme que ce soit et par aucun procédé, électronique ou mécanique, y compris la photocopie et les microfilms, sans l'accord écrit de l'éditeur.

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from the publisher.

International Electrotechnical Commission
Telefax: +41 22 919 0300

3, rue de Varembé Geneva, Switzerland
e-mail: inmail@iec.ch IEC web site <http://www.iec.ch>



Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

PRICE CODE

V

For price, see current catalogue

CONTENTS

	Page
FOREWORD	4
INTRODUCTION	5
Clause	
SECTION ONE – GENERAL	
1 Scope and object	6
2 Terminology and definitions	7
3 General requirements	10
5 Classification	11
6 Identification, marking and documents	11
SECTION TWO – ENVIRONMENTAL CONDITIONS	
10 Environmental conditions	13
SECTION THREE – PROTECTION AGAINST ELECTRIC SHOCK HAZARDS	
14 Requirements related to classification	14
17 Separation	14
19 Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS.....	14
SECTION FOUR – PROTECTION AGAINST MECHANICAL HAZARDS	
21 Mechanical strength.....	16
SECTION FIVE – PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION	
36 Electromagnetic compatibility.....	17
SECTION SIX – PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES	
SECTION SEVEN – PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS	
44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility	19
47 Electrostatic charges	20
49 Interruption of the power supply	20

Clause	Page
SECTION EIGHT – ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT	
50 Accuracy of operating data.....	21
51 Protection against hazardous output	38
SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS: ENVIRONMENTAL TESTS	
SECTION TEN – CONSTRUCTIONAL REQUIREMENTS	
54 General	42
56 Components and general assembly.....	44
Annexes	
L References – Publications mentioned in this standard	45
AA General guidance and rationale.....	47

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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: Electro-medical 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