

# INTERNATIONAL STANDARD

# IEC 60601-2-24

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1998-02

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## 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 de pompes et régulateurs de perfusion*

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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 A 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).