SLOVENSKI STANDARD
SIST EN 60601-2-24:1998

01-september-1998

Medicinska električna oprema - 2-24. del: Posebne varnostne zahteve za infuzijske črpalke in krmilnike (IEC 60601-2-24:1998)

Medical electrical equipment - Part 2-24: Particular requirements for the safety of infusion pumps and controllers (IEC 60601-2-24:1998)

Medizinische elektrische Geräte - Teil 2-24: Besondere Festlegungen für die Sicherheit von Infusionspumpen und Infusionsreglern (IEC 60601-2-24:1998)

Appareils électromédicaux - Partie 2-24: Règles particulières de sécurité des pompes et régulateurs de perfusion (CEI 60601-2-24:1998)

Ta slovenski standard je istoveten z: **EN 60601-2-24:1998**

ICS:

11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment

SIST EN 60601-2-24:1998 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-24

April 1998

ICS 11.040.20

Descriptors: Medical electrical equipment, infusion pump, infusion controller, safety requirements, protection against electric shock, protection against mechanical hazard, radiation protection, fire protection, environmental conditions

English version

Medical electrical equipment
Part 2: Particular requirements for the safety of infusion pumps and controllers
(IEC 60601-2-24:1998)

Appareils électromédicaux
Partie 2: Règles particulières de sécurité des pompes et régulateurs de perfusion
(CEI 60601-2-24:1998)

Medizinische elektrische Geräte
Teil 2: Besondere Festlegungen für die Sicherheit von Infusionspumpen und Steuergeräten
(IEC 60601-2-24:1998)

This European Standard was approved by CENELEC on 1998-04-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Foreword

The text of document 62D/250/FDIS, future edition 1 of IEC 60601-2-24, prepared by SC 62D, Electromedical equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-24 on 1998-04-01.

The following dates were fixed:

- latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 1999-01-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2001-01-01

CLC/TC 62 notes to the text of IEC 60601-2-24:

1) Where the phrase "ISO class III water for medical use" is used it should be replaced by "water, Grade III, according to ISO 3696".

2) In figure 104b the syringe used in the test procedure needs to comply with ISO 7886-2.

Endorsement notice

The text of the International Standard IEC 60601-2-24:1998 was approved by CENELEC as a European Standard without any modification.

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

NOTE: When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
Addition to annex ZA of EN 60601-1:1990/A2:1995:				
IEC 60529	1989	Degrees of protection provided by enclosures (IP Code)	EN 60529	1991
IEC 60601-1	1988	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1	1990
			+ corr. July	1994
A1	1991		A1	1993
			+ corr. July	1994
A2	1995		A2[1)]	1995
			A13	1996
IEC 60601-1-2	1993	Medical electrical equipment Part 1: General requirements for safety 2. Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	1993
IEC 60651	1979	Sound level meters	EN 60651	1994
A1	1993		A1	1994
IEC 60804	1985	Integrating-averaging sound level meters		
+ A1	1989		EN 60804	1994
A2	1993		A2	1994
ISO 3696	1987	Water for analytical laboratory use Specification and test methods	EN ISO 3696	1995
ISO 3744	1994	Acoustics - Determination of sound power levels of noise sources using sound pressure - Engineering method in an essentially free field over a reflecting plane	EN ISO 3744	1995
ISO 7864	1993	Sterile hypodermic needles for single use	EN ISO 7864	1995

1) A2 includes corrigendum June 1995 to IEC 60601-1:1988/A2.

Publication	Year	Title	EN/HD	Year
ISO 7886-2	1996	Sterile hypodermic syringes for single use Part 2: Syringes for use with power-driven syringe pumps	-	-
ISO 8536-4	1987	Infusion equipment for medical use Part 4: Infusion sets for single use	-	-

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Annex ZB (informative)

Other international publications mentioned in this standard with the references of the relevant European publications

Publication	Year	Title	EN/HD	Year
Addition to annex ZB of EN 60601-1:1990/A2:1995:				
IEC 60521	1988	Class 0,5, 1 and 2 alternating-current watthour meters	EN 60521	1995
IEC 60801-1	1984	Electromagnetic compatibility for industrial-process measurement and control equipment Part 1 : General introduction	HD 481.1 S1	1987
IEC 60801-2	1991	Part 2: Electrostatic discharge requirements	EN 60801-2	1993
IEC 61000-4-3 (mod)	1995	Electromagnetic compatibility (EMC) Part 4: Testing and measurement techniques Section 3: Radiated, radio-frequency, electromagnetic field immunity test	EN 61000-4-3	1996
IEC 61000-4-4	1995	Section 4: Electrical fast transient/burst immunity test	EN 61000-4-4	1995

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

International Electrotechnical Commission 3, rue de Varembé Geneva, Switzerland
Telefax: +41 22 919 0300 e-mail: inmail@iec.ch IEC web site http: //www.iec.ch

Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

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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: 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