

ELEKTRILISED MEDITSIINISEADMED. OSA 2-24:  
ERINÕUDED INFUSIOONPUMPADE JA KONTROLLERITE  
ESMASELE OHUTUSELE JA OLULISTELE  
TOIMIMISNÄITAJATELE

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

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

See Eesti standard EVS-EN 60601-2-24:2015 sisaldab Euroopa standardi EN 60601-2-24:2015 ingliskeelset teksti.	This Estonian standard EVS-EN 60601-2-24:2015 consists of the English text of the European standard EN 60601-2-24:2015.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
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English Version

Medical electrical equipment - Part 2-24: Particular requirements  
for the basic safety and essential performance of infusion pumps  
and controllers  
(IEC 60601-2-24:2012)

Appareils électromédicaux - Partie 2-24: Exigences  
particulières pour la sécurité de base et les performances  
essentielles des pompes et régulateurs de perfusion  
(IEC 60601-2-24:2012)

Medizinische elektrische Geräte - Teil 2-24: Besondere  
Festlegungen für die Sicherheit einschließlich der  
wesentlichen Leistungsmerkmale von Infusionspumpen und  
Infusionsreglern  
(IEC 60601-2-24:2012)

This European Standard was approved by CENELEC on 2015-04-14. 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 CEN-CENELEC Management Centre or to any CENELEC member.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

## Foreword

The text of document 62D/1026/FDIS, future edition 2 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 approved by CENELEC as EN 60601-2-24:2015.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2016-01-14
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2018-04-14

This document supersedes EN 60601-2-24:1998.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive 93/42/EEC, see informative Annex ZZ, which is an integral part of this document.

## Endorsement notice

The text of the International Standard IEC 60601-2-24:2012 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following note has to be added for the standard indicated :

IEC 61000-4-2                      NOTE                      Harmonized as EN 61000-4-2.

## Annex ZA (normative)

### Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 When an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: [www.cenelec.eu](http://www.cenelec.eu).

#### **Annex ZA of EN 60601-1:2006 applies, except as follows:**

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
<b>Replacement in Annex ZA of EN 60601-1:2006:</b>				
IEC 60601-1-2 (mod)	2007	Medical electrical equipment -	EN 60601-1-2	2007
-	-	Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	+ corrigendum Mar.	2010
IEC 60601-1-6	2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	EN 60601-1-6	2010
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	EN 60601-1-8	2007
-	-		+ corrigendum Mar.	2010
<b>Addition to Annex ZA of EN 60601-1:2006:</b>				
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
-	-		+ corrigendum Mar.	2010
+ A1	2012		+ A1	2013
-	-		+ A1/AC	2014
-	-		+ A12	2014
ISO 3696	1987	Water for analytical laboratory use - Specification and test methods	EN ISO 3696	1995
ISO 7864	-	Sterile hypodermic needles for single use	EN ISO 7864	-
ISO 8536-4	-	Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed	EN ISO 8536-4	-

**Annex ZZ**  
(informative)

**Coverage of Essential Requirements of EU Directives**

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and within its scope the Standard covers all relevant essential requirements given in Annex I of EU Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

**WARNING:** Other requirements and other EU Directives can be applied to the products falling within the scope of this standard.

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## 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<sup>1</sup> 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

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.

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.

<sup>1</sup> The general standard is IEC 60601-1:2005+A1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.