

ELEKTRILISED MEDITSIINISEADMED. OSA 2-49:  
ERINÕUDED MULTIFUNKTSIONAALSE  
PATSIENDIMONITORIDE JA SÜSTEEMIDE ESMASELE  
OHUTUSELE JA OLULISTELE TOIMIMISNÄITAJATELE

Medical electrical equipment - Part 2-49: Particular  
requirements for basic safety and essential  
performance of multifunction patient monitoring  
equipment

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

See Eesti standard EVS-EN 60601-2-49:2015 sisaldab Euroopa standardi EN 60601-2-49:2015 ingliskeelset teksti.	This Estonian standard EVS-EN 60601-2-49:2015 consists of the English text of the European standard EN 60601-2-49:2015.
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English Version

**Medical electrical equipment - Part 2-49: Particular requirements  
for the basic safety and essential performance of multifunction  
patient monitoring equipment  
(IEC 60601-2-49:2011)**

Appareils électromédicaux - Partie 2-49: Exigences  
particulières pour la sécurité de base et les performances  
essentielles des appareils de surveillance multifonction des  
patients  
(IEC 60601-2-49:2011)

Medizinische elektrische Geräte - Teil 2-49: Besondere  
Festlegungen für die Sicherheit einschließlich der  
wesentlichen Leistungsmerkmale von multifunktionalen  
Patientenüberwachungsgeräten  
(IEC 60601-2-49:2011)

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Comité Européen de Normalisation Electrotechnique  
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## European foreword

The text of document 62D/886/FDIS, future edition 2 of IEC 60601-2-49, 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 60601-2-49:2015.

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) 2016-06-15
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2018-09-15

This document supersedes EN 60601-2-49:2001.

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 60601-2-49:2011 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 80601-2-56	NOTE	Harmonized as EN 80601-2-56.
IEC 62366	NOTE	Harmonized as EN 62366.

## 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><i>Replacement in Annex ZA of EN 60601-1:2006:</i></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 -	+ corrigendum Mar.	2010
		Collateral standard: Electromagnetic compatibility - Requirements and tests		
IEC 60601-1-8	2006	Medical electrical equipment -	EN 60601-1-8	2007
-	-	Part 1-8: General requirements for basic safety and essential performance -	+ corrigendum Mar.	2010
		Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems		
ISO 15223-1	2007	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied -	-	-
		Part 1: General requirements		

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
<b><i>Addition to Annex ZA of EN 60601-1:2006:</i></b>				
IEC 60601-2-2	2009	Medical electrical equipment -	EN 60601-2-2	2009
-	-	Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	+ A11	2011
IEC 60601-2-27	2011	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment	EN 60601-2-27	2014
IEC 60601-2-34	2011	Medical electrical equipment - Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment	EN 60601-2-34	2014

## **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 concerns the BASIC SAFETY and ESSENTIAL PERFORMANCE of MULTIFUNCTION PATIENT MONITORING EQUIPMENT. It amends and supplements IEC 60601-1 (third edition, 2005): *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, hereinafter referred to as the general standard.

The aim of this second edition is to bring this particular standard up to date with reference to the third edition of the general standard through reformatting and technical changes.

The requirements of this particular standard take priority over those of the general standard.

A “General guidance and rationale” for the requirements of this particular standard is included in Annex AA. It is considered that 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 AA does not form part of the requirements of this standard.