ELEKTRILISED MEDITSIINISEADMED. OSA 2-25: ERINÕUDED ELEKTROKARDIOGRAAFIDE ESMASELE OHUTUSELE JA OLULISTELE TOIMIMISNÄITAJATELE

Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 60601-2-25:2015 sisaldab Euroopa standardi EN 60601-2-25:2015 ingliskeelset teksti.	This Estonian standard EVS-EN 60601-2-25:2015 consists of the English text of the European standard EN 60601-2-25:2015.
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.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 23.10.2015.	Date of Availability of the European standard is 23.10.2015.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.50

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-25

October 2015

ICS 11.040.55; 11.040.99

Supersedes EN 60601-2-25:1995, EN 60601-2-51:2003

English Version

Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs (IEC 60601-2-25:2011)

Appareils électromédicaux - Partie 2-25: Exigences particulières pour la sécurité de base et les performances essentielles des électrocardiographes (IEC 60601-2-25:2011)

Medizinische elektrische Geräte - Teil 2-25: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Elektrokardiographen (IEC 60601-2-25:2011)

This European Standard was approved by CENELEC on 2015-09-15. 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.

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 CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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

Ref. No. EN 60601-2-25:2015 E

European foreword

The text of document 62D/944/FDIS, future edition 2 of IEC 60601-2-25, 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 60601-2-25:2015.

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 60601-2-25:1995 and EN 60601-2-51:2003.

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 60601-2-25:2011 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 60601-2-27	NOTE	Harmonized as EN 60601-2-27.
IEC 60601-2-47	NOTE	Harmonized as EN 60601-2-47.

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.

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

Publication	Year	Title	EN/HD	Year
Replacement in Annex ZA of EN 60601-1:2006:				
IEC 60601-1-2 (mod)	2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	2007
-	-		+ corrigendum Mar.	2010
Addition to Annex ZA of EN 60601-1:2006:				
IEC 60601-2-2	2009	Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	EN 60601-2-2	2009
-	-		+ A11	2011

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.

CONTENTS

INTRODUCTION

This particular standard concerns the BASIC SAFETY and ESSENTIAL PERFORMANCE of ELECTROCARDIOGRAPHIC 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.

This particular standard now includes the contents of the particular standard IEC 60601-2-51: *Medical electrical equipment – Part 2-51: Particular requirements for the safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs.*

Updating the particular standards to refer to the third edition of the general standard provided the opportunity to merge the first editions of IEC 60601-2-25 and IEC 60601-2-51 into one standard. Reformatting and technical changes were both made.

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

A “General guidance and rationale” for the more important requirements of this particular standard is included in Annex AA. Knowledge of the reasons for these requirements will not only facilitate 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, Annex AA does not form part of the requirements of this standard.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs

201.1 Scope, object and related standards

Clause 1 of the general standard[1] applies, except as follows:

201.1.1 * Scope

Replacement:

This particular standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of ELECTROCARDIOGRAPHS as defined in 201.3.63 intended by themselves or as a part of an ME SYSTEM, for the production of ECG REPORTS for diagnostic purposes, hereinafter referred to as ME EQUIPMENT.

Not included within the scope of this particular standard are:

a) the part of ME EQUIPMENT that provides vectorcardiographic loops;

b) ambulatory electrocardiographic ME EQUIPMENT covered by IEC 60601-2-47 where not intended for obtaining ECG REPORTS for diagnostic purposes;

c) cardiac monitors covered by IEC 60601-2-27 where not intended for obtaining ECG REPORTS for diagnostic purposes.

NOTE 1 For example. ME EQUIPMENT includes:

a) direct-writing ELECTROCARDIOGRAPHS;

b) other ME EQUIPMENT that produce ECG REPORTS for diagnostic purposes, e.g. patient monitors, defibrillators, exercise testing devices;

c) ELECTROCARDIOGRAPHS having a display that is remote from the PATIENT (e.g. via phone lines, networks or storage media). These ME EQUIPMENT or ME SYSTEMS are within the scope of this particular standard excluding transmission media.

NOTE 2 ME EQUIPMENT that provide selection between diagnostic and monitoring functions shall meet the requirements of the appropriate standard when configured for that function.

ME EQUIPMENT intended for use under extreme or uncontrolled environmental conditions outside the hospital environment or physician's office, such as in ambulances and air transport, shall comply with this particular standard. Additional standards may apply to ME EQUIPMENT for those environments of use.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular requirements for BASIC SAFETY and ESSENTIAL PERFORMANCE of ELECTROCARDIOGRAPHS as defined in 201.3.63.

201.1.3 Collateral standards

Addition:

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[1] The general standard is IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*