

ELEKTRILISED MEDITSIINISEADMED. OSA 2-47:
ERINÕUDED AMBULATOORSETE
ELEKTROKARDIOGRAAFIASÜSTEEMIDE ESMASELE
OHUTUSELE JA OLULISTELE TOIMIMISNÄITAJATELE

Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems

EESTI STANDARDI EESSÕNA

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See Eesti standard EVS-EN 60601-2-47:2015 sisaldab Euroopa standardi EN 60601-2-47:2015 ingliskeelset teksti.	This Estonian standard EVS-EN 60601-2-47:2015 consists of the English text of the European standard EN 60601-2-47:2015.
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English Version

**Medical electrical equipment - Part 2-47: Particular requirements
for the basic safety and essential performance of ambulatory
electrocardiographic systems
(IEC 60601-2-47:2012)**

Appareils électromédicaux - Partie 2-47: Exigences
particulières pour la sécurité de base et les performances
essentielles des systèmes d'électrocardiographie
ambulatoires
(IEC 60601-2-47:2012)

Medizinische elektrische Geräte - Teil 2-47: Besondere
Festlegungen für die Sicherheit einschließlich der
wesentlichen Leistungsmerkmale von ambulanten
elektrokardiographischen Systemen
(IEC 60601-2-47:2012)

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/963/FDIS, future edition 2 of IEC 60601-2-47, 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 60601-2-47:2015.

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 60601-2-47:2001.

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 60601-2-47:2012 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 60601-2-25	NOTE	Harmonized as EN 60601-2-25.
IEC 60601-2-27	NOTE	Harmonized as EN 60601-2-27.

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:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
<i>In Annex ZA of EN 60601-1:2006 replace IEC 60601-1-2 by:</i>				
IEC 60601-1-2 (mod)	2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance -	EN 60601-1-2	2007
-	-	Collateral standard: Electromagnetic compatibility - Requirements and tests	+ corrigendum Mar.	2010

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 AMBULATORY ELECTROCARDIOGRAPHIC SYSTEMS. 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 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 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.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems

201.1 Scope, object and related standards

Clause 1 of the general standard¹ applies, except as follows:

201.1.1 Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of AMBULATORY ELECTROCARDIOGRAPHIC SYSTEMS, hereafter referred to as ME SYSTEMS

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.

Within the scope of this standard are systems of the following types:

- a) systems that provide continuous recording and continuous analysis of the ECG allowing full re-analysis giving essentially similar results. The systems may first record and store the ECG and analyse it later on a separate unit, or record and analyse the ECG simultaneously. The type of storage media used is irrelevant with regard to this standard;
- b) systems that provide continuous analysis and only partial or limited recording not allowing a full re-analysis of the ECG.

The safety aspects of this standard apply to all types of systems falling in one of the above-mentioned categories.

If the AMBULATORY ELECTROCARDIOGRAPHIC SYSTEM offers automatic ECG analysis, minimal performance requirements for measurement and analysis functions apply. MEDICAL ELECTRICAL EQUIPMENT covered by IEC 60601-2-25 and IEC 60601-2-27 are excluded from the scope of this standard.

This standard does not apply to systems that do not continuously record and analyse the ECG (for example, 'intermittent event recorders').

201.1.2 Object

Replacement:

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