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Elektrisk utrustning för medicinskt bruk – Säkerhet och väsentliga prestanda – Del 2-47: Särskilda fordringar på EKG-system med kroppsburen registreringsutrustning (Holtersystem)

Medical electrical equipment –

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

Som svensk standard gäller europastandarden EN 60601-2-47:2015. Den svenska standarden innehåller den officiella engelska språkversionen av EN 60601-2-47:2015.

Nationellt förord

Europastandarden EN 60601-2-47:2015

består av:

- **europastandardens ikraftsättningsdokument**, utarbetat inom CENELEC
- **IEC 60601-2-47, Second edition, 2012 - Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems**

utarbetad inom International Electrotechnical Commission, IEC.

Standarden ska användas tillsammans med SS-EN 60601-1.

Tidigare fastställd svensk standard SS-EN 60601-2-47, utgåva 1, 2002, gäller ej fr o m 2018-04-14.

Standarder underlättar utvecklingen och höjer elsäkerheten

Det finns många fördelar med att ha gemensamma tekniska regler för bl a mätning, säkerhet och provning och för utförande, skötsel och dokumentation av elprodukter och elanläggningar.

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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.

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

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

CONTENTS

FOREWORD.....	4
INTRODUCTION.....	6
201.1 Scope, object and related standards.....	7
201.2 Normative references	9
201.3 Terms and definitions	9
201.4 General requirements.....	11
201.5 General requirements for testing of ME EQUIPMENT.....	12
201.6 Classification of ME EQUIPMENT and ME SYSTEMS	12
201.7 ME EQUIPMENT identification, marking and documents.....	12
201.8 Protection against electrical HAZARDS from ME EQUIPMENT.....	13
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS.....	14
201.10 Protection against unwanted and excessive radiation HAZARDS.....	14
201.11 Protection against excessive temperatures and other HAZARDS.....	14
201.12 Accuracy of controls and instruments and protection against hazardous outputs	14
201.13 HAZARDOUS SITUATIONS and fault conditions	38
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	38
201.15 Construction of ME EQUIPMENT	38
201.16 ME SYSTEMS.....	39
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS.....	39
202 Electromagnetic compatibility – Requirements and tests	40
Annexes	42
Annex AA (informative) Particular guidance and rationale.....	43
Bibliography.....	64
Index of defined terms used in this particular standard.....	65
Figure 201.101 – General test circuit for 201.12.4.4.....	29
Figure 201.102 – Test signal for input dynamic range test according to 201.12.4.4.101	30
Figure 201.103 – Test circuit for common mode rejection according to 201.12.4.4.103	33
Figure 201.104 – Test circuit for pacemaker pulse tolerance according to 201.12.4.4.109.....	37
Figure 202.101 – Test set-up for conductive emission test according to 202.6.1.1.2 and radiated emission and radiated immunity test according to 202.6.1.1.2 and 202.6.2.3.2.....	41
Table 201.101 – Distributed additional ESSENTIAL PERFORMANCE requirements	11
Table 201.102 – LEAD WIRE colour codes	13
Table 201.103 – Requirements for all arrhythmia algorithms	17
Table 201.104 – Requirements for algorithms with optional capabilities	18
Table 201.105 – Beat label classifications	22
Table 201.106 – Example of noise floor calculation results	24
Table 201.107 – Example of HRV test results	25
Table 201.108 – Run sensitivity summary matrix	25
Table 201.109 – Run positive predictivity summary matrix	26

Table AA.1 – Records to be included in a complete test.....	44
Table AA.2 – Example of a line-format, beat-by-beat performance report.....	48
Table AA.3 – Condensed beat-by-beat summary matrix containing 11 elements	49
Table AA.4 – Summary table (matrix format) of beat-by-beat comparison	49
Table AA.5 – Example of a line-format SHUTDOWN report.....	50
Table AA.6 – Example of a line-format report.....	51
Table AA.7 – Example of VF performance report	51
Table AA.8 – Example of false VF performance report.....	51
Table AA.9 – Example of a line-format couplet and run performance report	52
Table AA.10 – Example of device measurements of synthetic test patterns.....	53
Table AA.11 – Example of predicted ideal values for synthetic test patterns	54
Table AA.12 – Example of choice of test patterns	54
Table AA.13 – Example of RMS interval differences	57
Table AA.14 – Example of summary of frequency components	58

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –**Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems**

FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of 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, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). 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. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International standard IEC 60601-2-47 has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition published in 2001. It constitutes a technical revision. This edition was revised to align structurally with the 2005 edition of IEC 60601-1.

The text of this particular standard is based on the following documents:

FDIS	Report on voting
62D/963/FDIS	62D/980/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.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

- Requirements and definitions: roman type.
- *Test specifications: italic type.*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

- “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site under "<http://webstore.iec.ch>" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

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*.

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for AMBULATORY ELECTROCARDIOGRAPHIC SYSTEMS.

201.1.3 Collateral Standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-2 applies as modified in Clause 202. IEC 60601-1-3, IEC 60601-1-8 and IEC 60601-1-10 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). 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 or applicable collateral 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 or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

Clause 2 of the general standard applies, except as follows:

Amendment:

IEC 60601-1-2:2007, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.*