

**Elektrilised meditsiiniseadmed. Osa 2-2: Erinõuded  
kõrgsageduse kirurgiliste instrumentide ja  
kõrgsageduse kirurgiliste lisaseadmete esmasele  
ohutusele ja olulistele toimimisnäitajatele**

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

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 60601-2-2:2009 sisaldab Euroopa standardi EN 60601-2-2:2009 ingliskeelset teksti.

Standard on kinnitatud Eesti Standardikeskuse 31.07.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.

Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 20.05.2009.

Standard on kättesaadav Eesti standardiorganisatsioonist.

This Estonian standard EVS-EN 60601-2-2:2009 consists of the English text of the European standard EN 60601-2-2:2009.

This standard is ratified with the order of Estonian Centre for Standardisation dated 31.07.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.

Date of Availability of the European standard text 20.05.2009.

The standard is available from Estonian standardisation organisation.

ICS 11.040.30

**Võtmesõnad:** construction, definitions, electrical safety, high frequency surgery, instructions for use, medical electrical equipment, requirements, testing

### Standardite reprodutseerimis- ja levitamiseõigus kuulub Eesti Standardikeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonilisse süsteemi või edastamine ükskõik millises vormis või millisel teel on keelatud ilma Eesti Standardikeskuse poolt antud kirjaliku loata.

Kui Teil on küsimusi standardite autorikaitse kohta, palun võtke ühendust Eesti Standardikeskusega:  
Aru 10 Tallinn 10317 Eesti; [www.evs.ee](http://www.evs.ee); Telefon: 605 5050; E-post: [info@evs.ee](mailto:info@evs.ee)

### Right to reproduce and distribute Estonian Standards belongs to the Estonian Centre for Standardisation

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without permission in writing from Estonian Centre for Standardisation.

If you have any questions about standards copyright, please contact Estonian Centre for Standardisation:  
Aru str 10 Tallinn 10317 Estonia; [www.evs.ee](http://www.evs.ee); Phone: +372 605 5050; E-mail: [info@evs.ee](mailto:info@evs.ee)

English version

**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  
(IEC 60601-2-2:2009)**

Appareils électromédicaux -  
Partie 2-2: Exigences particulières  
pour la sécurité de base  
et les performances essentielles  
des appareils d'électrochirurgie  
à courant haute fréquence  
et des accessoires d'électrochirurgie  
à courant haute fréquence  
(CEI 60601-2-2:2009)

Medizinische elektrische Geräte -  
Teil 2-2: Besondere Festlegungen  
für die Sicherheit einschließlich  
der wesentlichen Leistungsmerkmale  
von Hochfrequenz-Chirurgiegeräten  
und HF-chirurgischem Zubehör  
(IEC 60601-2-2:2009)

This European Standard was approved by CENELEC on 2009-04-01. 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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

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

**CENELEC**

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

**Central Secretariat: Avenue Marnix 17, B - 1000 Brussels**

## Foreword

The text of document 62D/726/FDIS, future edition 5 of IEC 60601-2-2, prepared by SC 62D, Electromedical equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-2 on 2009-04-01.

This European Standard supersedes EN 60601-2-2:2007.

Revisions in EN 60601-2-2:2009 include new language for preconditioning accessories prior to insulation testing, refining the requirements for electromagnetic compatibility testing and correcting some of the equations used in deriving the thermal test for NEUTRAL ELECTRODES.

The following dates were fixed:

- |  |       |            |
|--|-------|------------|
| – latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement | (dop) | 2010-01-01 |
| – latest date by which the national standards conflicting with the EN have to be withdrawn   | (dow) | 2012-04-01 |

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive MDD (93/42/EEC). See Annex ZZ.

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.

Annexes ZA and ZZ have been added by CENELEC.

---

### **Endorsement notice**

The text of the International Standard IEC 60601-2-2:2009 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 60601-2-18 + A1      NOTE Harmonized as EN 60601-2-18:1996 + A1:2000 (not modified).

---

## Annex ZA (normative)

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

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

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

*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>Replace the references to IEC 60601-1-2 and IEC 60601-1-8 by:</b>				
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
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
<b>Addition:</b>				
IEC 61000-4-3	2006	Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test	EN 61000-4-3 + IS1	2006 2009
IEC 61000-4-6	2003	Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields	EN 61000-4-6 <sup>1)</sup> + corr. August + IS1	2007 2007 2009
CISPR 11 (mod)	2003	Industrial scientific and medical (ISM) radio-frequency equipment - Electromagnetic disturbance characteristics - Limits and methods of measurement	EN 55011 <sup>2)</sup>	2007

<sup>1)</sup> EN 61000-4-6:2007 includes A1:2004 + A2:2006 to IEC 61000-4-6:2003. It is superseded by EN 61000-4-6:2009, which is based on IEC 61000-4-6:2008.

<sup>2)</sup> EN 55011:2007 includes A1:2004 (mod) to CISPR 11:2003 (mod).

## **Annex ZZ** (informative)

### **Coverage of Essential Requirements of EC 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 as given in Annex I of the EC Directive 93/42/EEC.

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

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

This document is a preview generated by EVS

## CONTENTS

FOREWORD.....	4
INTRODUCTION.....	7
201.1 Scope, object and related standards .....	8
201.2 Normative references .....	9
201.3 Terms and definitions.....	10
201.4 General requirements.....	13
201.5 General requirements for testing of ME EQUIPMENT.....	14
201.6 Classification of ME EQUIPMENT and ME SYSTEMS .....	14
201.7 ME EQUIPMENT identification, marking and documents.....	14
201.8 Protection against electrical HAZARDS from ME EQUIPMENT.....	19
201.9 Protection against mechanical hazards of ME EQUIPMENT and ME SYSTEMS.....	33
201.10 Protection against unwanted and excessive radiation HAZARDS.....	33
201.11 Protection against excessive temperatures and other HAZARDS.....	34
201.12 Accuracy of controls and instruments and protection against hazardous outputs.....	35
201.13 HAZARDOUS SITUATIONS and fault conditions .....	41
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) .....	42
201.15 Construction of ME EQUIPMENT .....	42
201.16 ME SYSTEMS .....	46
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS .....	46
202 * Electromagnetic compatibility – Requirements and tests .....	46
208 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.....	47
Annexes .....	47
Annex AA (informative) Particular guidance and rationale.....	48
Annex BB (informative) ELECTROMAGNETIC DISTURBANCES created by HF SURGICAL EQUIPMENT .....	70
Bibliography.....	79
Figure 201.101 – Symbol used with an EARTH REFERENCED PATIENT CIRCUIT.....	14
Figure 201.102 – Symbol used with a HF ISOLATED PATIENT CIRCUIT .....	15
Figure 201.103 – Circuit suitable for testing compliance to 201.8.4.101 .....	20
Figure 201.104 – Measurement of HF LEAKAGE CURRENT with NEUTRAL ELECTRODE referenced to earth and load between electrodes .....	23
Figure 201.105 – Measurement of HF LEAKAGE CURRENT with NEUTRAL ELECTRODE referenced to earth and load from ACTIVE ELECTRODE to earth .....	24
Figure 201.106 – Measurement of HF LEAKAGE CURRENT with NEUTRAL ELECTRODE isolated from earth at HIGH FREQUENCY .....	25
Figure 201.107 – Measurement of HF LEAKAGE CURRENT from a BIPOLAR ELECTRODE .....	26
Figure 201.108 – Test apparatus for anchorages of cords of ACTIVE ACCESSORY.....	32
Figure 201.109 – Measurement of output power – MONOPOLAR output.....	37
Figure 201.110 – Measurement of output power – BIPOLAR output.....	38



Figure 201.111 – Method of testing feedback from one active output to another in simultaneous activation.....	41
Figure AA.1 – Example of various parts of an HF surgical system.....	49
Figure AA.2 – CREST FACTOR vs. peak voltage .....	53
Figure AA.3 – Example of PATIENT circuit with NEUTRAL ELECTRODE referenced to earth at operating frequencies .....	57
Figure BB.1 – E-FIELD EMISSIONS test setup.....	73
Figure BB.2 – H-FIELD EMISSIONS test setup .....	74
Figure BB.3 – Conducted EMISSIONS test setup .....	75
Figure BB.4 – Unit ad hoc test .....	77
Figure BB.5 – Power cord ad hoc test.....	78
Figure BB.6 – ACCESSORY cord ad hoc test .....	78
Table 201.101 – Colours of indicator lights and their meaning for HF SURGICAL EQUIPMENT .....	15
Table 201.102 – Maximum output powers in SINGLE FAULT CONDITIONS .....	40
Table 201.103 – Test currents by weight range.....	44
Table AA.1 – Summary of measured current and durations for 25 TUR procedures.....	65
Table AA.2 – Summary of measured currents and durations for general surgical procedures .....	66
Table BB.1 – Worst case emissions of spark gap type HF SURGICAL EQUIPMENT .....	76
Table BB.2 – Worst case emissions of non-spark gap (modern) HF SURGICAL EQUIPMENT .....	76

## INTRODUCTION

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of high frequency surgical equipment.

This particular standard 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 (see 201.1.4).

The requirements are followed by specifications for the relevant tests.

A "Particular guidance and rationale" section giving some explanatory notes, where appropriate, about the more important requirements is included in annex AA.

Clauses or subclauses for which there are explanatory notes in annex AA are marked with an asterisk (\*).

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 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

#### 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 International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of HF SURGICAL EQUIPMENT as defined in 201.3.222.

HF SURGICAL EQUIPMENT having a RATED OUTPUT POWER not exceeding 50 W (for example for micro-COAGULATION, or for use in dentistry or ophthalmology) is exempt from certain of the requirements of this particular standard. These exemptions are indicated in the relevant requirements.

##### 201.1.2 Object

*Replacement:*

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for HF SURGICAL EQUIPMENT as defined in 201.3.222.

##### 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 2 of this particular standard.

IEC 60601-1-2 and IEC 60601-1-8 apply as modified in Clauses 202 and 208 respectively. IEC 60601-1-3, IEC 60601-1-10 and IEC 60601-1-11<sup>2)</sup> 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

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

<sup>2)</sup> IEC 60601-1-11, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment* (in preparation).