SLOVENSKI STANDARD
SIST EN IEC 60601-2-2:2018/oprA1:2022

01-junij-2022

Medicinska električna oprema - 2-2. del: Posebne zahteve za osnovno varnost in bistvene lastnosti visokofrekvenčne kirurške opreme in visokofrekvenčnega kirurškega pribora - Dopolnilo A1

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

Medizinische elektrische Geräte - Teil 2-2: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Hochfrequenz-Chirurgiegeräten

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

Ta slovenski standard je istoveten z: **EN IEC 60601-2-2:2018/prA1:2022**

ICS:

11.040.30	Operacijski instrumenti in materiali	Surgical instruments and materials

SIST EN IEC 60601-2-2:2018/oprA1:2022 en

62D/1944/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER:	
IEC 60601-2-2/AMD1 ED6	
DATE OF CIRCULATION:	CLOSING DATE FOR VOTING:
2022-04-15	**2022-07-08**
SUPERSEDES DOCUMENTS:	
62D/1861/CD, 62D/1902A/CC	

IEC SC 62D : ELECTROMEDICAL EQUIPMENT

SECRETARIAT:	SECRETARY:
United States of America	Ms Ladan Bulookbashi
OF INTEREST TO THE FOLLOWING COMMITTEES:	PROPOSED HORIZONTAL STANDARD: ☐ Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary.

FUNCTIONS CONCERNED:

☐ EMC ☐ ENVIRONMENT ☐ QUALITY ASSURANCE ☒ SAFETY

☒ SUBMITTED FOR CENELEC PARALLEL VOTING	☐ NOT SUBMITTED FOR CENELEC PARALLEL VOTING
Attention IEC-CENELEC parallel voting The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting. The CENELEC members are invited to vote through the CENELEC online voting system.	

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

TITLE:

Amendment 1 - 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

PROPOSED STABILITY DATE: 2027

NOTE FROM TC/SC OFFICERS:

The 6th Edition of IEC 60601-2-2 was published in 2017. This amendment is intended to align the standard to IEC 60601-1:2005/AMD2:2020. Additional issues reported from the National Committees and other interested parties since the publication in 2017 are addressed. National Committees are invited to submit votes and comments on the amended parts at this stage.

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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

AMENDMENT 1

FOREWORD

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Amendment 1 to IEC 60601-2-2:2017 has been prepared by subcommittee 62D: Electromedical Equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this Amendment is based on the following documents:

Draft	Report on voting
XX/XX/XXXX	XX/XX/XXX

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this Amendment is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/standardsdev/publications/.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

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

INTRODUCTION TO THE AMENDMENT

The International Electrotechnical Commission (IEC) draws attention to the fact that it is claimed that compliance with this document may involve the use of a patent. IEC takes no position concerning the evidence, validity, and scope of this patent right.

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Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights other than those in the patent database. IEC shall not be held responsible for identifying any or all such patent rights.

The 6th Edition of IEC 60601-2-2 was published in 2017. This amendment is intended to align the standard to IEC 60601-1:2005/AMD2:2020. Additionally, this amendment is intended to address several issues reported from the national committees, including but not limited to:

- Requirement for including the length of an accessory in the instructions for use
- Clarification of test setup for HF LEAKAGE CURRENTS
- Considering modes with high DUTY CYCLES above 45% in the risk management
- Including text of the interpretation sheet 62D/1703/INF regarding the HIGH CURRENT MODE to annex AA

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

AMENDMENT 1

201.1 Scope, object and related standards

In footnote 1 to the first sentence, replace “IEC 60601-1:2005/AMD1:2012” with “IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020”

201.1.3 Collateral standards

Replace the second paragraph with:

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 and IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2, apply as modified in Clauses 202 and 208 respectively. IEC 60601-1-3, IEC 60601-1-10, IEC 60601-1-11 and IEC 60601-1-12 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.2 Normative references

Update the following normative references:

Replace “IEC 60601-1-2:2014” with “IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020”

Replace “IEC 60601-1-8:2006+AMD1:2012” with “IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020”

Replace CISPR 11:2015 with CISPR 11:2019

201.3.220 HIGH FREQUENCY

Add the following note:

Note 1 to entry: HIGH FREQUENCY (HF) and radio frequency (RF) are considered as equivalent in the context of this standard as long as the frequency is within the range defined in this definition.

201.4.2.3.101 * Evaluating risk

Add the following text

Additionally, the impact on the heating under the NEUTRAL ELECTRODE shall be considered within RISK ANALYSIS for any mode with a duty cycle above 45% according to its intended use even if the HEATING FACTOR is below 30A²s in any 60s interval.

201.4.11 Power input

Replace the text of this paragraph with the following:

Replacement of first dash in compliance tests:

- The HF SURGICAL EQUIPMENT shall be operated in the manner (combination of operating setting, load, etc.) which creates the greatest steady state input current. Input current is measured and compared with the markings and the contents of the technical

description.

201.7.8.1 Colours of indicator lights

With reference to table 2 in the general standard, the meaning of the following colours are modified as follows:

Table 201.101 – Colours of indicator lights and their meaning for HF SURGICAL EQUIPMENT

Amendment

Name	On when	Indicator light	Alarm indicator light	Accompanied by sound	Operator requirement
Warning	Hazardous situation	Red, flashing or not	-	- [c,d]	Immediate response by the operator is required, for example, a fault in the patient circuit
Cutting mode		Yellow, flashing or not	-	Yes [e]	-

Addition

Name	On when	Indicator light	Alarm indicator light	Accompanied by sound	Operator requirement
Coagulation mode		Blue, flashing or not	-	Yes [e]	-

[e] As defined in 201.12.4.2.101

201.7.9.2.2.101 Additional information in instructions for use

In the first sentence of paragraph c), add an 's' to the word "instruction" because it is plural.

201.7.9.2.14 * Accessories, supplementary equipment, used material

Add new item:

k) the length of the ACCESSORY and its cord.

201.7.9.3.1 * General

Add the following note:

Note : The manufacturer can describe specific behaviour of the HF SURGICAL EQUIPMENT, e.g. short circuit protection

201.8.7.1. General requirements

Add the following note after the last sentence:

Note: This may require temporary internal modifications (e.g. Bridging of relay contacts) to be made to the HF SURGICAL EQUIPMENT

201.8.7.3.101 Thermal effects of HF LEAKAGE CURRENT

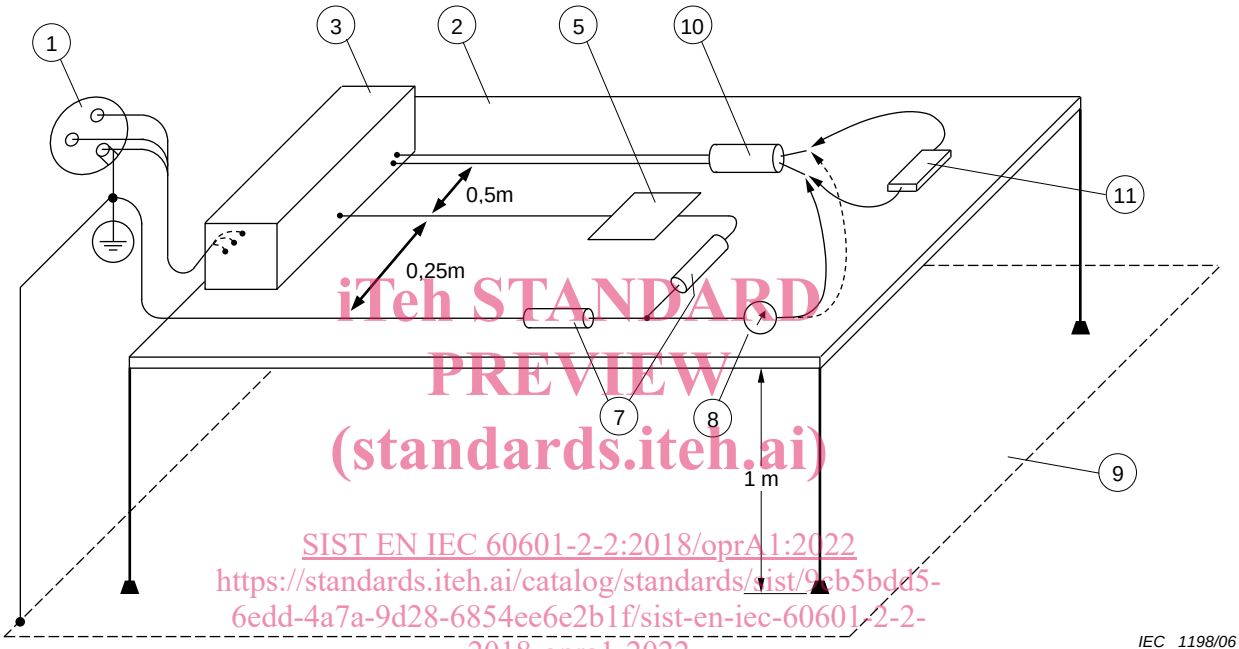
2) for MONOPOLAR HF ISOLATED PATIENT CIRCUITS

Replace the sentence beginning with "The HF SURGICAL EQUIPMENT is set up as shown in Figure 201.106,…" with the following:

The HF SURGICAL EQUIPMENT is set up as shown in Figure 201.106. Each electrode is tested with the output first being unloaded and then repeated with the output loaded at the RATED LOAD.

3) For BIPOLAR HF PATIENT CIRCUITS

Replace figure 201.107 with the following figure



Key

1 SUPPLY MAINS
2 Table, made of insulating material
3 HF SURGICAL EQUIPMENT
5 NEUTRAL ELECTRODE, metallic or in contact with metal foil of the same size
7 Measuring resistance, 200 Ω
8 HF current meter
9 Earthed conductive plane
10 Activated BIPOLAR ACCESSORY
11 Load resistance as required with HF power measuring device

Figure 201.107 – Measurement of HF LEAKAGE CURRENT from a BIPOLAR ACCESSORY

Replace the sentence beginning with "The test is conducted with the output…" in the third section with the following:

The test is conducted with the output first being unloaded or with the maximum load that produces an HF output and then repeated with the output loaded at the RATED LOAD.

201.8.8.3.102 ACTIVE ACCESSORY HF leakage

Add the following note at the end of paragraph a)

Note: In this paragraph, ‘d’ is the outer diameter of an insulation with a circular cross section. It has to be noted that the current formula can only be used for ACTIVE ACCESSORIES with circular cross section. For an ACTIVE ACCESSORY with a non-circular cross section, a value ‘d’ has to be calculated from the circumference ‘c’ of the original shape. In this case, the value d corresponds to the circumference divided by π.
$d = c / \pi$

201.12.4.3.101 Output reduction means

Replace the first sentence with the following:

Except as provided for in 201.7.9.2.2.101 a) item 7, and 201.7.9.3.1. – 5th dash, for each HF SURGICAL MODE, HF SURGICAL EQUIPMENT shall incorporate means to enable the output power to be reduced to not more than 5 % of the RATED OUTPUT POWER or 10 W, whichever is smaller (see also 201.12.1.102).

201.12.4.4.102 Output power during simultaneous activation

Remove the line: “For HF SURGICAL EQUIPMENT as defined in 201.12.2 c)”

Before the sentence starting with “The output under test is activated at 20 %”, add the following: For HF SURGICAL EQUIPMENT as defined in 201.12.2 c) 1)

Before the sentence starting with “The output under test is activated at 50 %”, add the following: For HF SURGICAL EQUIPMENT as defined in 201.12.2 c) 2)

202 Electromagnetic disturbances – Requirements and tests

Update the following normative reference:

IEC 60601-1-2:2014 with IEC 60601-1-2:2014/AMD1:2020

202.2 Normative references

Update reference “IEC 60601-2-2:2016” with “IEC 60601-2-2:2017 and IEC 60601-2-2:2017/AMD1:202x”

202.3 Terms and definitions

Update reference “IEC 60601-2-2:2016” with “IEC 60601-2-2:2017 and IEC 60601-2-2:2017/AMD1:202x”

202.8 Electromagnetic IMMUNITY requirements for ME EQUIPMENT and ME SYSTEMS

202.8.1 General

Update the reference “IEC 60601-1-2” *with* “IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020”

202.101 Index of defined terms

Replace all occurrences of “IEC 60601-2-2:2016” *with* “IEC 60601-2-2:2017 and IEC 60601-2-2:2017/AMD1:202x”