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תקן ישראלי ת"י 60601 חלק 2.2

תמוז התשע"ח – יולי 2018

טיוטה לגיליון תיקון מס' 1

אוגוסט 2023

ציוד חשמלי לשימוש רפואי: דרישות מיוחדות לבטיחות בסיסית ולביצועים חיוניים של ציוד לניתוח הפועל בתדר גבוה ושל אבזרים לניתוח הפועלים בתדר גבוה

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

מכון התקנים הישראלי
The Standards Institution of Israel

רח' חיים לבנון 42, תל-אביב 6997701, טל' 03-6465154, פקס' 03-6412762, www.sii.org.il

גיליון תיקון זה הוכן ואושר על ידי הוועדה הטכנית 5801 – ציוד חשמלי לשימוש רפואי, בהרכב זה:

איגוד לשכות המסחר	-	יואב אסולין
המועצה הישראלית לצרכנות	-	מיכאל שיזף
מינוי אישי	-	ולנטין ויינטראוב, יוסי פרי פז
מינוי אישי – מעבדה	-	אירנה אנטונוב
משרד הבריאות	-	אלכסנדר וילנסקי (יו"ר)
משרד הכלכלה והתעשייה	-	שלומי אביסרור
רשות ההסתדרות לצרכנות	-	גבריאל זרוק

כמו כן תרם להכנת גיליון התיקון דני אבן-חן.

זיוה שלו ריכזה את עבודת הכנת גיליון התיקון.

הודעה על גיליון תיקון

גיליון תיקון זה, למעט השינויים והתוספות הלאומיים המצוינים בו,
זהה לגיליון התיקון של הנציבות הבין-לאומית לאלקטרוטכניקה

IEC 60601-2-2:2017/AMD1:2023-02

גיליון תיקון זה מעדכן את
התקן הישראלי ת"י 60601 חלק 2.2 מיולי 2018

עדכניות התקן

התקנים הישראליים עומדים לבדיקה מזמן לזמן, ולפחות אחת לחמש שנים, כדי להתאימם להתפתחות המדע והטכנולוגיה.
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תוקף התקן

תקן ישראלי על עדכוניו נכנס לתוקף החל ממועד פרסומו ברשומות.
יש לבדוק אם התקן רשמי או אם חלקים ממנו רשמיים. תקן רשמי או גיליון תיקון רשמי (במלואם או בחלקם) נכנסים לתוקף 60 יום מפרסום ההודעה ברשומות, אלא אם בהודעה נקבע מועד מאוחר יותר לכניסה לתוקף.

סימון בתו תקן

כל המייצר מוצר, המתאים לדרישות התקנים הישראליים החלים עליו, רשאי, לפי היתר ממכון התקנים הישראלי, לסמנו בתו תקן:

מכון התקנים הישראלי

זכויות יוצרים

הקדמה לגיליון התיקון הישראלי

גיליון תיקון ישראלי זה הוא גיליון התיקון של הנציבות הבין-לאומית לאלקטרוטכניקה IEC 60601-2-2:2017/AMD1 מפברואר 2023, שאושר כגיליון תיקון ישראלי בשינויים ובתוספות לאומיים.

גיליון התיקון של הנציבות הבין-לאומית לאלקטרוטכניקה מובא להלן בשפה האנגלית.

גיליון תיקון ישראלי זה מתקן גם את התקן הישראלי ת״י 60601 חלק 2.2 מיולי 2018.

שינויים לחלק העברי של התקן:

עמוד השער

בכותרת העליונה של עמוד השער, בשורה השנייה, המילים ״IEC 60601-2-2 – Edition 6.0: 2017-03״ יושמטו.

עמוד ההודעות של התקן

הודעה על מידת התאמת התקן הישראלי לתקנים או למסמכים זרים (ראו בתחילת עמוד ההודעות של התקן)
המשפט הראשון בהודעה, ״תקן ישראלי זה זהה לתקן של הנציבות הבין-לאומית לאלקטרוטכניקה״, יושמט, ובמקומו ייכתב:
תקן ישראלי זה, למעט השינויים והתוספות הלאומיים המצוינים בו, זהה לתקן של הנציבות הבין-לאומית לאלקטרוטכניקה

הקדמה לתקן הישראלי

- בשורה השנייה, המילים ״שאושר כלשונו כתקן ישראלי״ יושמטו, ובמקומן ייכתב:
  שאושר כתקן ישראלי בשינויים ובתוספות לאומיים.
- בפסקה השנייה, בפירוט רכיבי התקן, לאחר התבליט הראשון יוסף:
  - פירוט השינויים והתוספות הלאומיים לסעיפי התקן הבין-לאומי (בעברית)

חלות התקן ומטרתו (תרגום סעיף 201.1.1 – חלות וסעיף 201.1.2 – מטרה של התקן הבין-לאומי)
הערת שוליים (1)
השורה השלישית בהערה, ״השינויים והתוספות הלאומיים אינם רלוונטיים לתקן ישראלי זה (ת״י 60601 חלק 2.2)״ תושמט.

- בסוף החלק העברי של התקן יוסף:

פירוט השינויים והתוספות הלאומיים לסעיפי התקן הבין-לאומי

בכל מקום בתקן הבין-לאומי שבו מאוזכרים התקנים הבין-לאומיים המפורטים בטבלה שלהלן, חלים לחלופין תקנים ישראליים בהתאמה, כמפורט להלן:

הערת הבהרה: המשמעות היא שניתן לעמוד בתקן הבין-לאומי המאוזכר, או לחלופין בתקן הישראלי המאוזכר, בהתאמה.

התקן הבין-לאומי המאוזכר	התקן הישראלי החל לחלופין
IEC 60601-1-2:2014 IEC 60601-1-2:2014/AMD1:2020	ת״י 60601 חלק 1.2 (2021) - ציוד חשמלי לשימוש רפואי: דרישות כלליות לבטיחות בסיסית ולביצועים חיוניים – תקן נִלווה: הפרעות אלקטרומגנטיות – דרישות ובדיקות
IEC 60601-1-8:2006 IEC 60601-1-8:2006/AMD1:2012 IEC 60601-1-8:2006/AMD2:2020	ת״י 60601 חלק 1.8 [2015 לרבות ג״ת 1 (2021)] - ציוד חשמלי לשימוש רפואי: דרישות כלליות לבטיחות בסיסית ולביצועים חיוניים – תקן נלווה: דרישות כלליות, בדיקות והנחיות עבור מערכות אזעקה בציוד רפואי-חשמלי ובמערכות רפואיות-חשמליות
CISPR 11:2015 CISPR 11:2015/AMD1:2016 CISPR 11:2015/AMD2:2019	ת״י 961 חלק 11 [2016 לרבות ג״ת 1 (2020)] - תאימות אלקטרומגנטית: ציוד תעשייתי, מדעי ורפואי – אופייני הפרעות בתדר רדיו – גבולות ושיטות מדידה

201.2. Normative references

לסעיף יוסף:

תקנים ישראליים

- ת״י 60601 חלק 1.2 (2021) – ציוד חשמלי לשימוש רפואי: דרישות כלליות לבטיחות בסיסית ולביצועים חיוניים – תקן נִלווה: הפרעות אלקטרומגנטיות – דרישות ובדיקות
- ת״י 60601 חלק 1.8 [2015 לרבות ג״ת 1 (2021)] – ציוד חשמלי לשימוש רפואי: דרישות כלליות לבטיחות בסיסית ולביצועים חיוניים – תקן נלווה: דרישות כלליות, בדיקות והנחיות עבור מערכות אזעקה בציוד רפואי-חשמלי ובמערכות רפואיות-חשמליות
- ת״י 961 חלק 11 [2016 לרבות ג״ת 1 (2020)] – תאימות אלקטרומגנטית: ציוד תעשייתי, מדעי ורפואי – אופייני הפרעות בתדר רדיו – גבולות ושיטות מדידה

IEC 60601-2-2

Edition 6.0 2023-02

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 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

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

IEC 60601-2-2:2017-03/AMD1:2023-02(en-fr)

IEC Secretariat
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

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IEC 60601-2-2

Edition 6.0 2023-02

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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: Particular medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems.

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

Draft	Report on voting
62D/2010/FDIS	62D/2021/RVD

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/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.

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INTRODUCTION to Amendment 1

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.

201.1 Scope, object and related standards

Replace, in footnote 1 to the first sentence, "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 existing second paragraph with the following:

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/AMD2:2020, 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

Replace the existing reference to IEC 60601-1-2:2014 with the following:

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*
IEC 60601-1-2:2014/AMD1:2020

Replace the existing reference to IEC 60601-1-8:2006 with the following:

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*
IEC 60601-1-8:2006/AMD1:2012
IEC 60601-1-8:2006/AMD2:2020

Delete the existing references to IEC 61000-4-3:2006 and IEC 6100-4-6:2013.

Replace the existing reference to CISPR 11:2015 with the following:

CISPR 11:2015, *Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement*
CISPR 11:2015/AMD1:2016
CISPR 11:2015/AMD2:2019

201.3.220
*** HIGH FREQUENCY**

Add, after the existing definition, the following new note:

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

201.4.2.3.101 * Evaluating risk

Add, at the end of the existing subclause, the following new 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 30 A^2s in any 60 s 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.

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

Replace the existing table with the following new table:

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

Name	On when	Indicator light[a]	Alarm indicator light	Accompanied by sound	Operator requirement
Warning [b]	Hazardous situation	Red, flashing or not	-	- [c]	Immediate response by the operator is required, for example, a fault in the patient circuit
CUTTING mode	CUTTING activation	Yellow, flashing or not	-	Yes [d]	-
COAGULATION mode	COAGULATION activation	Blue, flashing or not	-	Yes [d]	-
Ready for use	ME EQUIPMENT is ready for use	Green	-	-	-
Other	Situations other than that of red, yellow, blue or green	Any colour other than red, yellow, blue or green	-	-	-

[a] These indicator lights are INFORMATION SIGNALS and IEC 60601-1-8 requires that they be perceived as different than visual ALARM SIGNALS.

[b] Such warnings and cautions are frequently accompanied by a SAFETY SIGN.

[c] Sound may be utilized, but IEC 60601-1-8 requires that it be perceived as different than auditory ALARM SIGNALS.

[d] As defined in 201.12.4.2.101.

201.7.9.2.2.101 Additional information in instructions for use

*Replace, in the first sentence of item c), "*instruction*" with "*instructions*".*

201.7.9.2.14 * ACCESSORIES, supplementary equipment, used material

Add, before NOTE 101, the following new item:

k) * the length of the HF SURGICAL ACCESSORY.

201.7.9.3.1 * General

Add, at the end of the existing subclause, the following new note:

NOTE 101 The manufacturer can describe the specific behaviour of the HF SURGICAL EQUIPMENT, e.g. short circuit protection.

201.8.7.1 * General requirements

Add, after the last sentence, the following new note:

NOTE Temporary internal modifications to the HF SURGICAL EQUIPMENT can be used (e.g. bridging of relay contacts) to ensure the correct measurement of low-frequency LEAKAGE CURRENTS.

201.8.7.3.101 Thermal effects of HF LEAKAGE CURRENT

Replace, under item 2) for MONOPOLAR HF ISOLATED PATIENT CIRCUITS*, 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.

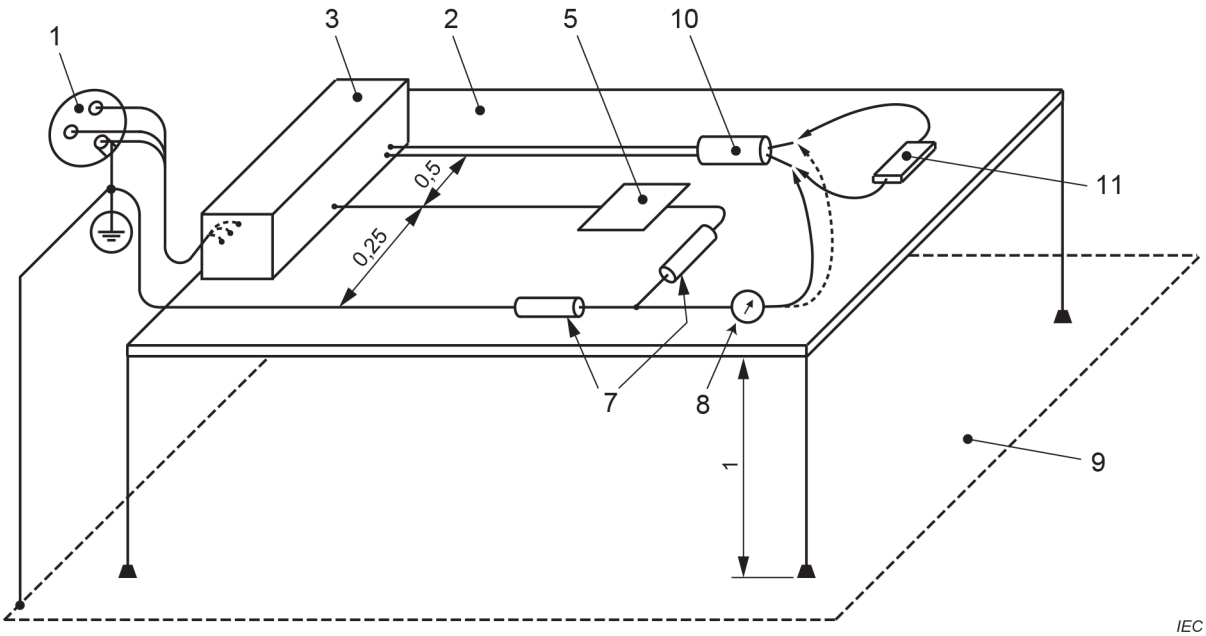
Replace, in item 3), the sentence beginning with "The test is conducted with the output…" in the fourth paragraph with the following:

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

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

Replace the existing figure with the following new figure:

Dimensions in meters



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

201.8.8.3.102 * ACTIVE ACCESSORY HF leakage

*Replace the existing sentence starting with "*The insulation applied to ACTIVE ACCESSORIES…" *with "*The insulation applied to ACTIVE ACCESSORIES, including ACTIVE ELECTRODE INSULATION and ACTIVE HANDLES, but excluding ACTIVE CONNECTORS, shall limit HF LEAKAGE CURRENT passing through the external surface of the insulation to less than $I_{leakage}$."

Add, at the end of item a), the following new note:

NOTE In this paragraph, '*d*' is the outer diameter of an insulation with a circular cross section. It is 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*' is 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

Delete the existing asterisk in the subclause title.

Replace the first sentence of this subclause 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

Delete the existing introductory sentence in the compliance statement: "For HF SURGICAL EQUIPMENT as defined in 201.12.2 c)".

Add, before the sentence starting with "The output under test is activated at 20 %", *the following new sentence* "For HF SURGICAL EQUIPMENT as defined in 201.12.2 c) 1):".

Add, before the sentence starting with "The output under test is activated at 50 %", *the following new sentence* "For HF SURGICAL EQUIPMENT as defined in 201.12.2 c) 2):".

202 * ELECTROMAGNETIC DISTURBANCES – Requirements and tests

*Replace "*IEC 60601-1-2:2014 applies" *with* "IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 apply".

202.2 Normative references

Replace the existing reference to "IEC 60601-2-2:2016" *with* "IEC 60601-2-2:2017 and IEC 60601-2-2:2017/AMD1:2023".

202.3 Terms and definitions

Replace the existing reference to "IEC 60601-2-2:2016" *with* "IEC 60601-2-2:2017 and IEC 60601-2-2:2017/AMD1:2023".

202.101 Index of defined terms

Replace the existing reference to "IEC 60601-2-2:2016" *with* "IEC 60601-2-2:2017 and IEC 60601-2-2:2017/AMD1:2023".

208 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

Replace "IEC 60601-1-8:2006 applies" *with* "IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 apply".

Definition 201.3.219 – HIGH CURRENT MODE

Add, after the existing text, the following new text:

The definition of HIGH CURRENT MODE is being misinterpreted with the effect that conventional HF SURGICAL EQUIPMENT used for many years with compatible, conventional NEUTRAL ELECTRODES without incidents are now erroneously declared as HIGH CURRENT MODE devices. This is not the intention of the document.

Users of the document should understand that

1) The load resistances specified in 201.7.9.3 and 201.12.1 do not define the INTENDED USE. The INTENDED USE is defined by the MANUFACTURER according to IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.44.
2) The MAXIMUM OUTPUT CURRENT is the RMS current at the lowest relevant impedance determined by the MANUFACTURER ignoring transients of less than 1 s when the device is operated according to the instructions for use.
3) The document requires that the MANUFACTURER performs a RISK ANALYSIS to review situations and reasonably foreseeable misuse that could result in current levels higher than the MAXIMUM OUTPUT CURRENT.

The HEATING FACTOR is calculated according to 201.3.218. The HEATING FACTOR is used to determine if a generator contains a HIGH CURRENT MODE or not according to 201.3.219.

Subclause 201.4.2.3.101 – Evaluating RISK

Add, after the existing text, the following new text:

The requirements for conventional NEUTRAL ELECTRODES are based on data with a maximum duty cycle of 45 % (see rationale for 201.15.101.5). For modes that are used with higher duty cycles according to their intended use, this is addressed in risk management.

Subclause 201.7.9.2.14 – ACCESSORIES, supplementary equipment, used material

Add, after the existing text of Subclause 201.7.9.2.14 j), the following new item:

Subclause 201.7.9.2.14 k)

HF SURGICAL ACCESSORIES act as antennas from an EMC point of view, so the user needs the length to ensure length compatibility between the HF SURGICAL EQUIPMENT and the accessory.

Subclause 201.8.8.3.101 – ACTIVE ACCESSORY insulation

Replace the first sentence of the existing note with the following:

This subclause was completely redrafted in the 5th Edition of this document to cover only dielectric strength of the various parts of ACTIVE ACCESSORY insulation, independent from any particular HF SURGICAL EQUIPMENT.

Subclause 201.12.4.3.101 – Output reduction means

Delete the existing title and text.

Clause 202 – ELECTROMAGNETIC DISTURBANCES – Requirements and tests

Replace, in the fourth existing paragraph, the first sentence with "During the immunity tests, the MANUFACTURER will need to specify how compliance to the standard is checked."

Add, at the end of the existing subclause, the following new text:

HF SURGICAL EQUIPMENT is evaluated regarding EMC utilizing ACTIVE ACCESSORIES that represent the least favourable configuration according to IEC 60601-1-2. This configuration is considered when determining the maximum permissible length of accessories (see 201.7.9.2.2.101 i)). The relevant length is for example the fully extended length between the ACTIVE CONNECTOR and the distal end of the ACTIVE ELECTRODE.

The MANUFACTURER may choose not to re-evaluate EMC, if previously completed EMC testing can be shown to be applicable by objective evidence for the configuration.

HF SURGICAL ACCESSORIES, including ASSOCIATED EQUIPMENT, that include active electronic circuits should be evaluated for EMC.

Ensuring compatibility between HF SURGICAL EQUIPMENT and HF SURGICAL ACCESSORIES is an OPERATOR responsibility.

Bibliography

Add the following new references [19] to [22] as follows:

[19] IEC 60601-1-3, *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment*

[20] IEC 60601-1-10, *Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers*

[21] 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*

[22] IEC 60601-1-12, *Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*

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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

3, rue de Varembé
PO Box 131
CH-1211 Geneva 20
Switzerland

Tel: + 41 22 919 02 11
info@iec.ch
www.iec.ch