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Medical electrical equipment -
Part 2-91: Particular requirements for basic safety and essential performance of non-thermal plasma wound treatment equipment

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Medical electrical equipment - Part 2-91: Particular requirements for basic safety and essential performance of non-thermal plasma wound treatment equipment

FOREWORD

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IEC 60601-2-91 has been prepared by subcommittee 62D: Particular medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems. It is an International Standard.

The text of this International Standard is based on the following documents:

Draft	Report on voting
62D/2297/FDIS	62D/2314/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 International Standard 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.

In this document, 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 AND IEC 60601-1:2005/AMD2:2020, in this document or as noted: SMALL CAPITALS.

In referring to the structure of this document, the term

– "clause" means one of the eighteen 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 document are preceded by the term "Clause" followed by the clause number. References to subclauses within this document are by number only.

In this document, 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 document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;

– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;

– "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 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, or

– revised.

INTRODUCTION

The minimum safety requirements specified in this document are considered to provide for a practical degree of safety in the operation of NON-THERMAL PLASMA WOUND TREATMENT EQUIPMENT.

This document amends and supplements IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*.

The requirements are followed by specifications for the relevant tests.

This document is to define the safety of, and provides the test methods to evaluate the HAZARDS of NON-THERMAL PLASMA WOUND TREATMENT ME. This would include the following potential HAZARDS: plasma gas temperature, O_3 level, nitrogen oxide level, electrical_leakage, and electrical insulation. This document will be limited to NON-THERMAL PLASMA WOUND TREATMENT EQUIPMENT.

Conventional MEDICAL ELECTRICAL EQUIPMENT treats wounds individually using electrical stimulation, heat, radiation, and light. Unlike conventional medical devices, plasma medical devices treat wounds using a combination of REACTIVE SPECIES, electrons, ions, electromagnetic fields, visible light and (v)UV radiation. There is no guidance on safety and the measurement methods for NON-THERMAL PLASMA WOUND TREATMENT EQUIPMENT in comparison with other conventional medical equipment. Therefore, a standard for NON-THERMAL PLASMA WOUND TREATMENT EQUIPMENT can provide safety and ESSENTIAL PERFORMANCE.

201.1 Scope, object and related standards

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, Clause 1, applies, except as follows:

201.1.1 Scope

Replacement:

This part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of NON-THERMAL PLASMA WOUND TREATMENT EQUIPMENT and NON-THERMAL PLASMA WOUND TREATMENT ACCESSORIES.

NON-THERMAL PLASMA WOUND TREATMENT EQUIPMENT and NON-THERMAL PLASMA WOUND TREATMENT ACCESSORIES are not intended to supply heat to the PATIENT. They are used to treat chronic and acute wounds and biological tissue as well as diverse skin and itching diseases.

HAZARDS inherent in the intended physiological function of PLASMA WOUND TREATMENT EQUIPMENT and NON-THERMAL PLASMA WOUND TREATMENT ACCESSORIES within the scope of this document are covered by specific requirements in 7.2.13 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

This document does not apply to ME EQUIPMENT intended for the haemostasis of biological tissue (see IEC 60601-2-2[1][1] and IEC 60601-2-76[2]).

201.1.2 Object

Replacement:

The object of this document is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for NON-THERMAL PLASMA WOUND TREATMENT EQUIPMENT and NON-THERMAL PLASMA WOUND TREATMENT ACCESSORIES, as defined in 201.3.204 and 201.3.203.

201.1.3 Collateral standards

Addition:

This document refers to those applicable collateral standards that are listed in Clause 2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and Clause 201.2 of this document.

IEC 60601-1-3[3] and IEC 60601-1-10[4] do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Addition:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

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1 Numbers in square brackets refer to the Bibliography.

A requirement of a particular standard takes priority over IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

The numbering of clauses and subclauses of this document corresponds to that of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020) 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 document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this document addresses the content of Clause 4 of the 60601-1-3 collateral standard, etc.). The changes to the text of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are specified by the use of the following words:

"*Replacement*" means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is replaced completely by the text in this document.

"*Addition*" means that the text of this document is additional to the requirements of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard.

"*Amendment*" means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is amended as indicated by the text of this document.

Subclauses, figures or tables which are additional to those of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered starting from 201.101. However, due to the fact that definitions in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered 3.1 through 3.154, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Where there is no corresponding clause or subclause in this document, the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this document.

201.2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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.

Addition:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

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