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Medical electrical equipment —

Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source

Appareils électromédicaux —

Partie 2-31: Exigences particulières pour la sécurité de base et les performances essentielles des stimulateurs cardiaques externes à source d'énergie interne

ICS: 11.040.40

Member bodies are requested to consult relevant national interests in IEC/SC 62D before casting their ballot to the e-Balloting application.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source

FOREWORD

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IEC 80601-2-31 has been prepared by a Joint Working Group of IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice, and ISO subcommittee SC6: Active implants, of ISO technical committee 150: Implants for surgery. It is an International Standard.

This publication is published as a double logo standard.

This first edition of IEC 80601-2-31 cancels and replaces the third edition of IEC 60601-2-31 published in 2020. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

- The requirements regarding essential performance have been simplified;
- The allowed colours for indicators have been modified from those specified in the general standard;

- Requirements for terminal markings have been clarified;
- The required instructions for use regarding estimated service time for a fully charged battery have been modified;
- The test for saline exposure has been clarified as an additional test;
- The requirements related to immunity from ELECTROSTATIC DISCHARGE have been modified;
- Additional rationale for all changes.

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

Draft	Report on voting
62D/XX/FDIS	62D/XX/RVD

Full information on the voting for the approval of this International Standard can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by TBD P members out of TBD having cast a vote.

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

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 THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, 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 document are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard 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 b 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.

NOTE The attention of users of this document is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

IMPORTANT – The "colour inside" logo on the cover page of this document indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

INTRODUCTION

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of EXTERNAL PACEMAKERS with an internal power source.

Basically, CARDIAC PACEMAKERS treat cardiac arrhythmias. Such arrhythmias reduce cardiac output and can lead to confusion, dizziness, loss of consciousness and death. The objective of pacing is to restore cardiac rhythm and output appropriate to the PATIENT's physiological needs.

There are two distinct families of CARDIAC PACEMAKERS, implantable PACEMAKERS and EXTERNAL PACEMAKERS. EXTERNAL PACEMAKERS are used to pace PATIENTS temporarily prior to implanting an implantable PACEMAKER as well as for temporary pacing related to other medical PROCEDURES, e.g. open heart surgery.

CARDIAC PACEMAKERS differ in the various ways in which they sense and maintain cardiac activity in different circumstances. The simplest model stimulates the atrium or ventricle independently of the cardiac activity; others detect atrial or ventricular activity and stimulate the atrium or ventricle as and when this is necessary; others, more complex, detect the spontaneous heart activity and stimulate appropriately the atrium and/or the ventricle. Certain PACEMAKERS work on pre-set frequency values, amplitudes and impulse duration. Others can have several values for parameters.

Standards for EXTERNAL PACEMAKERS require attention to information which will aid in developing and applying these devices. It is through these aspects of standardization that the central role of clinical experience should be, or has been, acknowledged. The ability to predict how a PACEMAKER will perform in a specific PATIENT based on testing of a device to a set of technical criteria is limited.

This particular standard does not take into consideration the specific safety aspects of EXTERNAL PACEMAKERS that are connected to a SUPPLY MAINS while simultaneously connected to the PATIENT.

This particular standard amends and supplements IEC 60601-1:2005 and 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 performanc*, hereinafter referred to as the general standard.

The requirements are followed by specifications for the relevant tests.

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

An inventory of the PATIENT's safety posed by EXTERNAL PACEMAKERS and a rationale for the safety requirements contained in this particular standard are given in Annex AA. It is considered that knowledge of the reasons for these requirements will not only facilitate the proper application of this particular standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, Annex AA does not form part of the requirements of this document.

In accordance with IEC directives concerning standards developed jointly with ISO, the numbering of this particular standard has been changed from IEC 60601 -2-31 to IEC 80601-2-31. This document constitutes the first edition of IEC 80601 -2-31.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source

201.1 Scope, object and related standards

Clause 1 of the general standard[1] applies, except as follows:

201.1.1 * Scope

Replacement:

This part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of EXTERNAL PACEMAKERS powered by an INTERNAL ELECTRICAL POWER SOURCE, hereafter referred to as ME EQUIPMENT.

This document applies to PATIENT CABLES as defined in 201.3.209, but does not apply to LEADS as defined in 201.3.206.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT within the scope of this document are not covered by specific requirements in this document except in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the general standard.

This document does not apply to the implantable parts of ACTIVE IMPLANTABLE MEDICAL DEVICES covered by ISO 14708-1. This document does not apply to EXTERNAL PACEMAKERS which can be connected directly or indirectly to a SUPPLY MAINS.

This document does not apply to transthoracic and oesophageal pacing ME EQUIPMENT and antitachycardia ME EQUIPMENT.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for EXTERNAL PACEMAKERS as defined in 201.3.205.

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 60601-1-2:2014 + AMD1:2020 applies as modified in Clause 202. IEC 60601-1-3, IEC 60601-1-9, 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.

201.1.4 Particular standards

Replacement:

[1] The general standard is 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.*