

Medical electrical equipment
Part 2.4: Particular requirements for the basic safety and essential
performance of cardiac defibrillators

Amendment No. 1

International adoption identical

Publishing and Approval Dates

Council of Standards Australia Approval: 31 May 2022

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Summary

This Amendment applies to the following elements:

- Front cover
- Preface
- Amendment 1

Amendment Details

AS 60601.2.4:2018 is amended as follows. The amendments should be inserted in the locations as instructed.

Element	Instruction / New text
Front cover	Top right-hand corner, after AS 60601.2.4:2018 <i>add</i> : (Incorporating Amendment No. 1)
Preface	After the first paragraph, <i>add</i> the following: Amendment No. 1 to this Standard was prepared by the Standards Australia Committee HE-003, Medical Electrical Equipment. <i>Delete</i> fourth paragraph and <i>replace</i> with the following: This Standard is identical with, and has been reproduced from, IEC 60601-2-4:2010 (ED. 3.0), <i>Medical electrical equipment, Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators</i> and its Amendment 1 (2018), which has been added at the end of the source text.
Amd 1 (new)	After Index of defined terms used in this collateral standard, <i>add</i> the following Amendment No. 1 (2018):

FOREWORD

This amendment 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:

FDIS	Report on voting
62D/1549/FDIS	62D/1555/RVD

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

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the stability date indicated on the IEC website under "<http://webstore.iec.ch>" in the data related to the specific publication. At this date, the publication will be

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- withdrawn,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

201.1.1 * Scope

Replace the fourth existing paragraph by the following new paragraph:

This particular standard does not apply to implantable DEFIBRILLATORS, remote control DEFIBRILLATORS, or separate stand-alone cardiac monitors (which are standardized by IEC 60601-2-27:2011 [2]¹). Cardiac monitors which use separate ECG monitoring electrodes are not within the scope of this standard unless they are used as the sole basis for AED rhythm recognition detection or beat detection for synchronized cardioversion. DEFIBRILLATOR electrodes as described in 201.108 can also be used for ECG monitoring; however, due to the larger electrode area, the requirements of IEC 60601-2-27 are not applicable for DEFIBRILLATOR ELECTRODES.

201.2 Normative references

Replace, in the "Amendment" section, the existing reference IEC 60601-1-2, including its title, by the following new reference:

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*

¹ Numbers in square brackets refer to the bibliography.

Replace, in the "Addition" section, the existing reference "ISO 15223-1:2007" by "ISO 15223-1:2016"

Add, in the "Addition" section, the following new reference:

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

201.3 Terms and definitions

Replace the first existing paragraph by the following new paragraph:

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 apply, except as follows:

201.3.202

Replace the existing Note 2 by the following new note:

NOTE 2 Such ME EQUIPMENT may also include other monitoring or therapeutic functions (e.g. transcutaneous pacing).

201.3.203

Add, after the definition, the following new note:

NOTE The CHARGING CIRCUITS for defibrillation and pacing functions may be separate or combined.

201.3.204

Replace the existing definition and note by the following new definition and note:

electrode intended to deliver an electrical pulse for the purpose of cardiac defibrillation and which may also be used to provide transcutaneous pacing and other monitoring functions

NOTE DEFIBRILLATOR ELECTRODES may be internal or external and disposable or reusable.

201.3.206

Add, after the definition, the following new note:

NOTE The DISCHARGE CIRCUITS for defibrillation and pacing functions may be separate or combined.

201.3.209

Replace the existing note by the following new note:

NOTE The energy storage devices for defibrillation and pacing functions may be separate or combined.

Add, after 201.3.220, the following new term and definition:

201.3.221

PACER

EXTERNAL TRANSCUTANEOUS PACEMAKER

optional circuit within the DEFIBRILLATOR intended to stimulate the heart by a series of electrical pulses via electrodes applied to the PATIENT's skin

201.7.2.103 Disposable defibrillator electrodes

Replace, in item a) of the existing paragraph, the reference "ISO 15223-1:2007" by "ISO 15223-1:2016".

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Add, after 201.8.3, the following new subclause:

201.8.5.3 * MAXIMUM MAINS VOLTAGE

Addition:

Where the MAXIMUM MAINS VOLTAGE has been assigned the value of 250 V, and the derivation of test voltage from the value of the MAXIMUM MAINS VOLTAGE includes a 110 % multiplier, that multiplier shall not apply.

201.8.7.1 General requirements

Replace the existing instruction by the following new instruction:

Replacement of b) dash 4 with:

201.8.8.3 * Dielectric strength

Replace, in the "Addition" section, the first existing paragraph by the following new paragraph:

For the DEFIBRILLATOR and PACER high-voltage circuits, between high-voltage parts of opposite polarity and high-voltage to low-voltage circuits, the following tests shall replace those of the general standard.

Delete, in the second paragraph in the "Addition" section, the words "during discharging".

Replace, in the fifth paragraph of Test 1, the term "DEFIBRILLATOR" by "DEFIBRILLATOR or PACER".

Replace, in the seventh paragraph of Test 1, the term "DEFIBRILLATORS" by "DEFIBRILLATORS or PACERS".

Add, after the last paragraph of the Subclause, the following new paragraph:

For the dielectric tests of the general standard, the WORKING VOLTAGE is determined without regard to the presence of defibrillation or pacing voltages.

201.8.9.1.5 * ME EQUIPMENT RATED for high altitudes

Replace the existing paragraph by the following new paragraph:

General standard subclause 8.9.1.5 does not apply to DEFIBRILLATORS rated for use at altitudes up to 5 000 m.

201.8.9.1.101 * DEFIBRILLATOR ELECTRODES, high-voltage circuits and cables

Delete, in the note, the words "but is under consideration for future application".

Replace the existing item b), excluding the compliance statement, by the following new paragraphs:

- b) * Except for components where the adequacy of ratings can be demonstrated (e.g. by component manufacturers' ratings or by the dielectric strength tests of 201.8.8.3 of this standard) the CREEPAGE DISTANCES and AIR CLEARANCES of insulation between the DEFIBRILLATOR or PACER high-voltage circuits and other parts, and between different parts of the high-voltage circuits, shall be at least 3 mm/kV.