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SOUTH AFRICAN NATIONAL STANDARD

Medical electrical equipment

Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests

This national standard is the identical implementation of IEC 60601-1-2:2007, and is adopted with the permission of the International Electrotechnical Commission.

WARNING
This standard references other documents normatively.

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Table of changes

Change No.	Date	Scope
IEC interpretation sheet	2010	Included to clarify the subclauses on ME equipment and ME systems.

National foreword

This South African standard was prepared by National Committee SABS/TC 072, *Safety of electrical appliances and electronic equipment,* in accordance with procedures of the SABS Standards Division, in compliance with annex 3 of the WTO/TBT agreement.

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Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

Appareils électromédicaux – Partie 1-2: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Compatibilité électromagnétique – Exigences et essais

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MEDICAL ELECTRICAL EQUIPMENT –

Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

INTERPRETATION SHEET

This interpretation sheet has been prepared by SC 62A: Common aspects of electrical equipment used in medical practice.

The text of this interpretation sheet is based on the following documents:

ISH	Report on voting
62A/685/ISH	62A/694/RVD

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

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Subclause 6.2.2.2 e) (ESD IMMUNITY)

(This is also applicable to Subclause 36.202.2 b) 5) in IEC 60601-1-2:2001[1)].)

This subclause states the following:

The test may be performed with the ME EQUIPMENT or ME SYSTEM powered at any one of its NOMINAL input voltages and frequencies.

This is clarified by the following:

The test may be performed at any input power voltage and frequency within the ME EQUIPMENT or ME SYSTEM RATED voltage and frequency range. If the ME EQUIPMENT or ME SYSTEM is tested at one power input voltage and one power input frequency meeting this specification, it is not necessary to re-test at additional voltages or frequencies.

Subclause 6.2.3.2 j) (Radiated RF IMMUNITY)

(This is also applicable to Subclause 36.202.3 b) 10) in IEC 60601-1-2:2001.)

This subclause states the following:

The test may be performed with the ME EQUIPMENT or ME SYSTEM powered at any one of its NOMINAL input voltages and frequencies.

This is clarified by the following:

1) A consolidated edition 2.1 exists (withdrawn) including IEC 60601-1-2:2001 and its Amendment 1 (2004).

The test may be performed at any power input voltage and frequency within the ME EQUIPMENT or ME SYSTEM RATED voltage and frequency range. If the EQUIPMENT or SYSTEM is tested at one power input voltage and one power input frequency meeting this specification, it is not necessary to re-test at additional voltages or frequencies.

Subclause 6.2.4.2 e) (EFT/burst IMMUNITY)

(This is also applicable to Subclause 36.202.4 b) 5) in IEC 60601-1-2:2001.)

This subclause states the following:

For ME EQUIPMENT and ME SYSTEMS that have, for power input, multiple voltage settings or autoranging voltage capability, the test is performed at the minimum and maximum RATED input voltages. The test may be performed with the ME EQUIPMENT or ME SYSTEM powered at any one of its NOMINAL power frequencies.

This is clarified by the following:

For ME EQUIPMENT and ME SYSTEMS that have, for power input, multiple voltage settings or autoranging voltage capability, the test shall be performed at the minimum and maximum ME EQUIPMENT or ME SYSTEM RATED power input voltages. The test may be performed at any power input frequency within the ME EQUIPMENT or ME SYSTEM RATED range. If the ME EQUIPMENT or ME SYSTEM is tested at power input voltages and a power input frequency meeting these specifications, it is not necessary to re-test at additional voltages or frequencies.

Subclause 6.2.5.2 f) (Surge IMMUNITY)

(This is also applicable to Subclause 36.202.5 b) 6) in IEC 60601-1-2:2001.)

This subclause states the following:

For ME EQUIPMENT and ME SYSTEMS that have, for power input, multiple voltage settings or autoranging voltage capability, the test is performed at the minimum and maximum RATED input voltages. The test may be performed with the ME EQUIPMENT or ME SYSTEM powered at any one of its NOMINAL power frequencies.

This is clarified by the following:

For ME EQUIPMENT and ME SYSTEMS that have, for power input, multiple voltage settings or autoranging voltage capability, the test shall be performed at the minimum and maximum ME EQUIPMENT or ME SYSTEM RATED power input voltages. The test may be performed at any power input frequency within the ME EQUIPMENT or ME SYSTEM RATED range. If the ME EQUIPMENT or ME SYSTEM is tested at power input voltages and a power input frequency meeting these specifications, it is not necessary to re-test at additional voltages or frequencies.

Subclause 6.2.6.2 j) (Conducted RF IMMUNITY)

(This is also applicable to Subclause 36.202.6 b) 10) in IEC 60601-1-2:2001.)

This subclause states the following:

The test may be performed with the ME EQUIPMENT or ME SYSTEM powered at any one of its NOMINAL input voltages and frequencies.

This is clarified by the following:

The test may be performed at any power input voltage and frequency within the ME EQUIPMENT or ME SYSTEM RATED voltage and frequency range. If the EQUIPMENT or SYSTEM is