

Australian/New Zealand Standard™

Medical electrical equipment

**Part 2.25: Particular requirements for
the basic safety and essential
performance of electrocardiographs**



AS/NZS IEC 60601.2.25:2016

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HE-003, Medical Electrical Equipment. It was approved on behalf of the Council of Standards Australia on 20 May 2016 and by the New Zealand Standards Approval Board on 20 April 2016.

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the basic safety and essential
performance of electrocardiographs**

Originally in Australia as AS 3201.3—1971.
Previous and first New Zealand edition AS/NZS 3200.2.25:1993.
Completely revised and redesignated as AS/NZS IEC 60601.2.25:2016.

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE-003, Medical Electrical Equipment, to supersede AS/NZS 3200.2.25:1993, *Approval and test specification—Medical electrical equipment, Part 2.25: Particular requirements for safety—Electrocardiographs*.

The objective of this Standard is to establish particular requirements for basic safety and essential performance of electrocardiographs, which are defined as equipment and associated lead wires and electrodes intended for the production of ECG reports for diagnostic purposes.

The requirements of this Standard supplement the general requirements specified in AS/NZS IEC 60601.1, *Medical electrical equipment, Part 1: General requirements for basic safety and essential performance*. This Standard is intended to be read in conjunction with AS/NZS IEC 60601.1:2015.

This Standard is identical with, and has been reproduced from, IEC 60601-2-25, Ed. 2.0 (2011), *Medical electrical equipment, Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs*.

As this Standard is reproduced from an International Standard, a full stop substitutes for a comma when referring to a decimal marker.

References to International Standards should be replaced by references to Australian or Australian/New Zealand Standards, as follows:

<i>Reference to International Standard</i>	<i>Australian/New Zealand Standard</i>
IEC	AS/NZS IEC
60601 Medical electrical equipment	60601 Medical electrical equipment
60601-2-2 Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	60601.2.2 Part 2.2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

Only normative references that have been adopted as Australian or Australian/New Zealand Standards have been listed.

The term 'informative' has been used in this Standard to define the application of the annex to which it applies. An 'informative' annex is only for information and guidance.

CONTENTS

201.1	Scope, object and related standards.....	8
201.2	Normative references	10
201.3	Terms and definitions	10
201.4	General requirements.....	12
201.5	General requirements for testing of ME EQUIPMENT.....	12
201.6	Classification of ME EQUIPMENT and ME SYSTEMS	13
201.7	ME EQUIPMENT identification, marking and documents.....	13
201.8	Protection against electrical HAZARDS from ME EQUIPMENT.....	16
201.9	Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS.....	21
201.10	Protection against unwanted and excessive radiation HAZARDS.....	21
201.11	Protection against excessive temperatures and other HAZARDS.....	21
201.12	Accuracy of controls and instruments and protection against hazardous outputs.....	22
201.13	HAZARDOUS SITUATIONS and fault conditions.....	37
201.14	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS).....	37
201.15	Construction of ME EQUIPMENT	37
201.16	ME SYSTEMS.....	37
201.17	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS.....	37
202	Electromagnetic compatibility – Requirements and tests	38
Annexes	43
Annex AA (informative)	Particular guidance and rationale.....	44
Annex BB (informative)	ELECTRODES, their positions, identifications and colour codes	51
Annex CC (informative)	LEADS, their identification and colour codes (other than those specified in 201.12.4.102).....	53
Annex DD (informative)	Polarity of PATIENT LEADS (other than those specified in 201.12.4.102)	54
Annex EE (informative)	Additional marking of ELECTRODES.....	55
Annex FF (informative)	Definitions and rules for the measurement of ELECTROCARDIOGRAM.....	56
Annex GG (informative)	Calibration and test data sets.....	61
Annex HH (informative)	CTS test atlas.....	63
Bibliography	94
Index of defined terms used in this particular standard.....		95
Figure 201.101	– ELECTRODE position according to Frank	14
Figure 201.102	– Test of protection against the effects of defibrillation (differential mode) (see 201.8.5.5.1).....	19
Figure 201.103	– Test of protection against the effects of defibrillation (common mode) (see 201.8.5.5.1)	20
Figure 201.104	– Application of the test voltage between LEAD WIRES to test the energy delivered by the defibrillator.....	21

Figure 201.105 – Test circuit for COMMON MODE REJECTION and NOISE level	28
Figure 201.106 – General test circuit	30
Figure 201.107 – Triangular waveforms for test E of Table 201.107	32
Figure 201.108 – Input impulse signal and ELECTROCARDIOGRAPH response	32
Figure 201.109 – Circuit for test of linearity.....	34
Figure 201.110 – Result of linearity test.....	34
Figure 201.111 – Pacemaker overload test circuit.....	36
Figure 202.101 – Set-up for radiated and conducted emission test	39
Figure 202.102 – Set-up for radiated immunity test.....	40
Figure 202.103 – Test circuit for HF surgery protection measurement.....	42
Figure 202.104 – Test setup for HF surgery protection measurement.....	43
Figure BB.1a – LEADS and colours for fetal ECG (see Table BB.2)	52
Figure BB.1b – Positions of the ELECTRODES on the fetus for fetal ECG (see Table BB.2).....	52
Figure BB.2 – LEAD positions and colours for fetal scalp ECG (see Table BB.2)	52
Figure FF.1 – Normal ELECTROCARDIOGRAM.....	56
Figure FF.2 – Determination of global intervals (example)	57
Figure FF.3 – Waveform durations, isoelectric segments	58
Figure FF.4 – QRS complex with small R-wave(s) (see Figure FF.5, FF.6)	59
Figure FF.5 – Detail of small accepted R-wave	60
Figure FF.6 – Detail of small rejected R-wave.....	60
Figure HH.1 – Nomenclature of calibration ECGS	66
Figure HH.2 – Nomenclature of analytical ECGS	69
Table 201.101 – ESSENTIAL PERFORMANCE requirements	12
Table 201.102 – ELECTRODES, their position, identification and colour code.....	14
Table 201.103 – Protection against the effect of defibrillation (test conditions).....	18
Table 201.104 – Acceptable mean differences and standard deviations for global intervals and Q-, R-, S-durations on calibration and analytical ECGS	23
Table 201.105 – Acceptable mean differences and standard deviations for global durations and intervals for biological ECGS	23
Table 201.106 – LEADS and their identification (nomenclature and definition).....	25
Table 201.107 – Frequency response	31
Table 201.108 – PATIENT ELECTRODE connection for pacemaker pulse display test	37
Table AA.1 – ELECTRODE positions and electrical strength requirements	46
Table BB.1 – ELECTRODES, their positions, identifications and colour codes (other than described in 201.7.4.101, Table 201.106)	51
Table BB.2 – Other ELECTRODE-positions, identifications and colour codes not covered by this particular standard.....	51
Table DD.1 – ELECTRODE polarities	54
Table EE.1 – Recommended identification and colour code for a 14-wire PATIENT CABLE	55
Table GG.1 – CALIBRATION and analytical ECGS	61
Table GG.2 – Data set for testing of measurement and wave recognition accuracy of biological data – 100 selected ECGS of the CSE-study with their numbering in the CSE database, to be used in 201.12.1.101.3.2	62
Table HH.1 – Naming of signals (calibration ECGS)	67

Table HH.2 – Naming of signals (analytical ECGs) 68

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INTRODUCTION

This particular standard concerns the BASIC SAFETY and ESSENTIAL PERFORMANCE of ELECTROCARDIOGRAPHIC EQUIPMENT. It amends and supplements IEC 60601-1 (third edition, 2005): *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, hereinafter referred to as the general standard.

This particular standard now includes the contents of the particular standard IEC 60601-2-51: *Medical electrical equipment – Part 2-51: Particular requirements for the safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs*.

Updating the particular standards to refer to the third edition of the general standard provided the opportunity to merge the first editions of IEC 60601-2-25 and IEC 60601-2-51 into one standard. Reformatting and technical changes were both made.

The requirements of this particular standard take priority over those of the general standard.

A “General guidance and rationale” for the more important requirements of this particular standard is included in Annex AA. Knowledge of the reasons for these requirements will not only facilitate proper application of the 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 standard.

NOTES

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Medical electrical equipment

Part 2.25:

Particular requirements for the basic safety and essential performance of electrocardiographs

201.1 Scope, object and related standards

Clause 1 of the general standard¹ applies, except as follows:

201.1.1 * Scope

Replacement:

This particular standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of ELECTROCARDIOGRAPHS as defined in 201.3.63 intended by themselves or as a part of an ME SYSTEM, for the production of ECG REPORTS for diagnostic purposes, hereinafter referred to as ME EQUIPMENT.

Not included within the scope of this particular standard are:

- the part of ME EQUIPMENT that provides vectorcardiographic loops;
- ambulatory electrocardiographic ME EQUIPMENT covered by IEC 60601-2-47 where not intended for obtaining ECG REPORTS for diagnostic purposes;
- cardiac monitors covered by IEC 60601-2-27 where not intended for obtaining ECG REPORTS for diagnostic purposes.

NOTE 1 For example, ME EQUIPMENT includes:

- direct-writing ELECTROCARDIOGRAPHS;
- other ME EQUIPMENT that produce ECG REPORTS for diagnostic purposes, e.g. patient monitors, defibrillators, exercise testing devices;
- ELECTROCARDIOGRAPHS having a display which is remote from the PATIENT (e.g. via phone lines, networks or storage media). These ME EQUIPMENT or ME SYSTEMS are within the scope of this particular standard excluding transmission media.

NOTE 2 ME EQUIPMENT that provide selection between diagnostic and monitoring functions shall meet the requirements of the appropriate standard when configured for that function.

ME EQUIPMENT intended for use under extreme or uncontrolled environmental conditions outside the hospital environment or physician's office, such as in ambulances and air transport, shall comply with this particular standard. Additional standards may apply to ME EQUIPMENT for those environments of use.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular requirements for BASIC SAFETY and ESSENTIAL PERFORMANCE of ELECTROCARDIOGRAPHS as defined in 201.3.63.

201.1.3 Collateral standards

Addition:

¹ The general standard is IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.