

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 following are represented on Committee HE-003:

Australian and New Zealand College of Anaesthetists
Australian Dental Association
Australian Society of Anaesthetists
Canterbury District Health Board
College of Biomedical Engineering, Engineers Australia
Department of Defence
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Australian/New Zealand Standard™

Medical electrical equipment

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

Originated in Australia as AS 3201.3—1971.
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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 point 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.

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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

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:

- a) the part of ME EQUIPMENT that provides vectorcardiographic loops;
- b) ambulatory electrocardiographic ME EQUIPMENT covered by IEC 60601-2-47 where not intended for obtaining ECG REPORTS for diagnostic purposes;
- c) 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:

- a) direct-writing ELECTROCARDIOGRAPHS;
- b) other ME EQUIPMENT that produce ECG REPORTS for diagnostic purposes, e.g. patient monitors, defibrillators, exercise testing devices;
- c) ELECTROCARDIOGRAPHS having a display that 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*.

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 applies as modified in Clause 202. IEC 60601-1-3, IEC 60601-1-8 and IEC 60601-1-10 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) 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 particular standard addresses the content of Clause 4 of the 60601-1-2 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

“Replacement” means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

“Addition” means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

“Amendment” means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, etc.

The term “this standard” is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

NOTE Informative references are listed in the bibliography beginning on page 94.

Clause 2 of the general standard applies, except as follows:

Replacement:

IEC 60601-1-2:2007, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

Addition:

IEC 60601-2-2:2009, *Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*

201.3 Terms and definitions

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

201.3.63

MEDICAL ELECTRICAL EQUIPMENT

Replacement:

ELECTROCARDIOGRAPH

ME EQUIPMENT

equipment and associated LEAD WIRES and ELECTRODES intended for the production of ECG REPORTS for diagnostic purposes

Addition:

201.3.201

CENTRAL TERMINAL ACCORDING TO WILSON

CT

average potential of the R (RA), L (LA) and F (LL) ELECTRODES

201.3.202

CHANNEL

hardware and/or software selection of a particular electrocardiographic LEAD for purposes of display, recording, or transmission

201.3.203

DC OFFSET VOLTAGE

d.c. voltage appearing on ELECTRODES with respect to the NEUTRAL ELECTRODE resulting from ELECTRODE-skin voltages

201.3.204

COMMON MODE REJECTION

ability of the ELECTROCARDIOGRAPH including the PATIENT CABLE and ELECTRODES, high frequency FILTERS, protection networks, LEAD networks, amplifier input, etc., to discriminate between signals with differences between amplifier inputs (differential signal) and signals common to amplifier inputs (common signal), in the presence of ELECTRODE impedance imbalance

201.3.205**ECG REPORT**

a presentation (e.g. a hard copy print-out or a display) of an ELECTROCARDIOGRAM with associated data such as the date and time that ELECTROCARDIOGRAM was acquired, PATIENT identification etc.

201.3.206**EFFECTIVE RECORDING WIDTH**

width of the paper recording within which the signal of a CHANNEL can be recorded according to this particular standard

201.3.207**ELECTROCARDIOGRAM****ECG**

graphical presentation of one or more LEADS over time

201.3.208**ELECTRODE**

sensor in contact with a specified part of the body that is used to detect electrical activity

201.3.209**FILTER**

means, realized in hardware, firmware or software, to attenuate unwanted components in the signal being recorded, e.g. muscle action voltages in an ECG signal

201.3.210**GAIN**

ratio of the amplitude of the output signal to the amplitude of the input signal

NOTE GAIN is expressed in mm/mV.

201.3.211**LEAD**

voltage between ELECTRODES

201.3.212**LEAD WIRE**

cable connected between ELECTRODE and either a PATIENT CABLE or the ME EQUIPMENT

201.3.213**NEUTRAL ELECTRODE**

reference point for differential amplifiers and/or interference suppression circuits, not intended to be used to calculate any LEAD

201.3.214**NOISE**

unwanted signals of any frequency present in the ELECTROCARDIOGRAM

201.3.215**NORMAL GAIN**

GAIN of 10 mm/mV

201.3.216**PATIENT CABLE**

multiwire cable used to connect the LEAD WIRES to the ELECTROCARDIOGRAPH

201.4 General requirements

Clause 4 of the general standard applies, except as follows:

201.4.3 ESSENTIAL PERFORMANCE

Addition:

201.4.3.101 Additional ESSENTIAL PERFORMANCE requirements

Table 201.101 identifies essential performance requirements for electrocardiographs and the subclauses in which they are found.

Table 201.101 – ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
Defibrillation protection	201.8.5.5.1
ESSENTIAL PERFORMANCE of ME EQUIPMENT	201.12.1.101
FILTERS (including line frequency interference FILTERS)	201.12.4.105.3
Electrostatic discharge	202.6.2.2.1
Electric fast transients and bursts	202.6.2.4.1
Conducted disturbances	202.6.2.6.1
Electrosurgery interference	202.6.2.101

201.5 General requirements for testing of ME EQUIPMENT

Clause 5 of the general standard applies, except as follows:

201.5.3 * Ambient temperature, humidity, atmospheric pressure

Addition:

- aa) Tests are performed within a relative humidity range of 25 % to 95 % (without condensation).

201.5.4 Other conditions

Addition:

- aa) Unless otherwise stated, tests shall be carried out with the ACCESSORIES and the recording materials specified by the MANUFACTURER.
- bb) For ME EQUIPMENT with an INTERNAL ELECTRICAL POWER SOURCE, if the test result is affected by the INTERNAL ELECTRICAL POWER SOURCE voltage, then the test shall be performed using the least favourable INTERNAL ELECTRICAL POWER SOURCE voltage specified by the MANUFACTURER. If necessary for the purpose of conducting the test, an external battery or d.c. power supply may be used to provide the necessary test voltage.
- cc) The values used in test circuits, unless otherwise specified, shall have at least an accuracy as given below:
- resistors: ± 1 %;
 - capacitors: ± 10 %;
 - inductors: ± 10 %;
 - test voltages: ± 1 %

201.5.8 * Sequence of tests

Amendment:

Tests called for in 201.8.5.5.1 of this particular standard shall be carried out prior to the LEAKAGE CURRENT and dielectric strength tests of clauses B.20 and B.22 of Annex B of the general standard.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies, except as follows:

201.6.2 Protection against electric shock

Replacement of the last paragraph:

APPLIED PARTS shall be classified as TYPE CF APPLIED PARTS (see 7.2.10 and 8.3 of the general standard). APPLIED PARTS shall be classified as DEFIBRILLATION-PROOF APPLIED PARTS (see 8.5.5 of the general standard).

201.6.6 Mode of operation

Replacement:

ME EQUIPMENT shall be classified for CONTINUOUS OPERATION.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows:

201.7.4 Making of controls and instruments

Additional subclause:

201.7.4.101 * PATIENT CABLE and PATIENT CABLE to ME EQUIPMENT connector

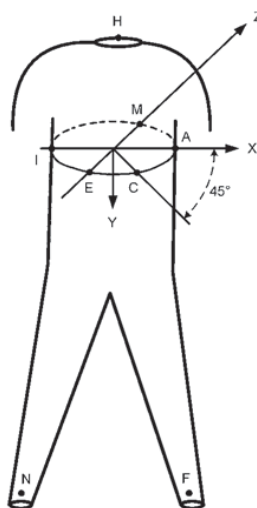
In order to minimize the possibility of incorrect connections, the PATIENT CABLE shall be permanently marked with one of the identifiers (ELECTRODE identifier and/or colour code) specified in Table 201.102;

Detachable LEAD WIRES shall be permanently marked on both ends with the identifiers (ELECTRODE identifier and/or colour code) specified in Table 201.102. For additional markings, see Annex BB.

The PATIENT CABLE to ME EQUIPMENT connector shall be constructed or marked so that the OPERATOR can identify the ME EQUIPMENT to which the PATIENT CABLE should be connected.

Table 201.102 – ELECTRODES, their position, identification and colour code

LEAD-System	CODE 1 (usually European)		CODE 2 (usually American)		Position on body surface
	ELECTRODE identifier	Colour code	ELECTRODE identifier	Colour code	
Limb	R	Red	RA	White	Right arm
	L	Yellow	LA	Black	Left arm
	F	Green	LL	Red	Left leg
Chest according to Wilson	C	White	V	Brown	Single movable chest ELECTRODE
	C1	White/red	V1	Brown/red	Fourth intercostal space at right border of sternum
	C2	White/yellow	V2	Brown/yellow	Fourth intercostal space at left border of sternum
	C3	White/green	V3	Brown/green	Fifth rib between C2 and C4
	C4	White/brown	V4	Brown/blue	Fifth intercostal space on left midclavicular line
	C5	White/black	V5	Brown/orange	Left anterior axillary line at the horizontal level of C4
	C6	White/violet	V6	Brown/violet	Left midaxillary line at the horizontal level of C4
Position according to Frank (see Figure 201.101)	I	Light blue/red	I	Orange/red	At the right midaxillary line ^a
	E	Light blue/yellow	E	Orange/yellow	At the front midline ^a
	C	Light blue/green	C	Orange/green	Between front midline and left midaxillary line at an angle of 45 degrees ^a
	A	Light blue/brown	A	Orange/brown	At the left midaxillary line ^a
	M	Light blue/black	M	Orange/black	At the back midline ^a
	H	Light blue/violet	H	Orange/violet	On the back of the neck
	F	Green	F	Red	On the left leg
	N or RF	Black	RL	Green	Right leg (neutral)
NOTE Additional recommendations are given in Annex BB and Annex EE.					
^a Located at the transverse level of the ventricles, if known, or otherwise at the fifth intercostal space.					



IEC 2246/11

Figure 201.101 – ELECTRODE position according to Frank

201.7.9.2 Instructions for use

Additional subclause:

201.7.9.2.101 Additional instructions for use

a) Advice shall be given on the following:

- 1) the INTENDED USE of the ELECTROCARDIOGRAPH including the environment of use. This disclosure shall include all the attributes of INTENDED USE such as, but not limited to, the following:
 - i) diagnostic application(s) for which the ELECTROCARDIOGRAPH is intended (e.g.: screening for cardiac abnormalities in the general population, detecting acute myocardial ischemia and infarction in chest pain PATIENTS, etc.);
 - ii) population(s) for whom the ELECTROCARDIOGRAPH is intended (e.g.: adults, children, infants, neonates, etc. – specify the age limits of the targeted population where applicable);
 - iii) location(s) for which the ELECTROCARDIOGRAPH is intended (e.g.: hospital, general physician's office, out-of-hospital locations such as ambulance, home-care, etc.).

If the ELECTROCARDIOGRAPH has more than one INTENDED USE with different attributes, all the INTENDED USES and associated attributes shall be disclosed;

- 2) instructions for connecting a POTENTIAL EQUALIZATION CONDUCTOR, if applicable;
- 3) that conductive parts of ELECTRODES and associated connectors for TYPE BF or CF APPLIED PARTS, including the NEUTRAL ELECTRODE, should not contact any other conductive parts including earth;
- 4) the specification (and type number, if necessary) of the PATIENT CABLE which needs to be used to provide protection against the effect of the discharge of a cardiac defibrillator and against high-frequency burns;
- 5) precautions to take when using a defibrillator on a PATIENT; a description of how the discharge of a defibrillator affects the ME EQUIPMENT; a warning that defibrillator protection requires use of MANUFACTURER specified ACCESSORIES including ELECTRODES, LEAD WIRES and PATIENT CABLES. The specification (or type-number) of such ACCESSORIES (see 201.8.5.5.1) shall be disclosed;
- 6) advice to the clinical OPERATOR regarding whether the ELECTROCARDIOGRAPH incorporates a means to protect the PATIENT against burns when used with HIGH-FREQUENCY (HF) SURGICAL EQUIPMENT. Advice shall be given regarding the location of ELECTRODES, LEAD WIRES, etc. to reduce the hazards of burns in the event of a defect in the HF SURGICAL EQUIPMENT'S NEUTRAL ELECTRODE connection;
- 7) the choice and application of specified PATIENT CABLES and LEAD WIRES; the choice and application of ELECTRODES;
- 8) caution to the OPERATOR regarding summation of LEAKAGE CURRENTS when several items of ME EQUIPMENT are interconnected.;
- 9) whether the ELECTROCARDIOGRAPH is suitable for DIRECT CARDIAC APPLICATION;
- 10) how to identify whether the ELECTROCARDIOGRAPH is inoperable (see 201.12.4.101);
- 11) precautions regarding any HAZARD that may be caused by the operation of a cardiac pacemaker or other electrical stimulators with the ELECTROCARDIOGRAPH.
- 12) where relevant, a statement that the ME EQUIPMENT is protected against malfunction caused by electrosurgery;
- 13) INTERNALLY POWERED ME EQUIPMENT: the minimum operating time of the ME EQUIPMENT shall be disclosed, provided that the battery is new and fully charged. If rechargeable batteries are used, the MANUFACTURER shall disclose the battery charge time from depletion to 90 % charge in NORMAL USE and battery conditioning, if applicable. Specific advice shall be given on how to determine when the battery needs to be replaced. In addition, the battery charging procedure shall also be disclosed;

- 14) * advice regarding testing of the ELECTROCARDIOGRAPH and ACCESSORIES on a daily basis (by the clinical OPERATOR) and on a scheduled basis (as a service activity);
- 15) simple fault finding methods for troubleshooting problems by which the clinical OPERATOR can locate problems if the ME EQUIPMENT appears to be functioning incorrectly.

NOTE This relates to simple OPERATOR difficulties, not to technical malfunctions.

b) MANUFACTURER shall disclose the following in the ACCOMPANYING DOCUMENTS:

- 1) whether the isoelectric segments within the QRS are included in or excluded from the Q-, R- or S-waves. The ACCOMPANYING DOCUMENTS shall specifically explain whether isoelectric parts (I-wave) after global QRS-onset or before global QRS-offset (K-wave) are included in the duration measurement of the respective adjacent waveform;
- 2) whether the ELECTROCARDIOGRAPH has to be configured with specific FILTER settings to pass the distortion test, and the effect of these FILTER settings have on ECG signal distortion as required in 201.12.4.107.1.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies, except as follows:

201.8.3 Classification of APPLIED PARTS

Replacement of items a), b), and c):

The APPLIED PART shall be a TYPE CF APPLIED PART.

201.8.5 Separation of parts

201.8.5.2.3 PATIENT leads

Addition:

Any detachable ELECTRODE connector of a LEAD WIRE shall, when separated from the ELECTRODE, have an air clearance between connector pins and a flat surface of at least 0,5 mm.

Compliance is checked by inspection.

201.8.5.5.1 * Defibrillation protection

Addition:

Protection against the effects of defibrillation shall be provided for ME EQUIPMENT.

For defibrillator testing the ME EQUIPMENT is operated using the PATIENT CABLES as specified by the MANUFACTURER.

The following requirements and tests apply in addition to the requirements and tests as specified in 8.5.5.1 of the general standard.

- **Common mode test**

Addition:

Within 5 s after exposure to the defibrillation voltage, the ME EQUIPMENT shall resume normal operation in the previous operating mode, without loss of any OPERATOR settings or stored

data, and shall continue to perform its intended function as specified in the ACCOMPANYING DOCUMENTS.

Compliance is checked according to Figure 201.103.

For ME EQUIPMENT of CLASS I, apply the test voltage between all LEAD WIRES, including the NEUTRAL ELECTRODE, connected together and the FUNCTIONAL EARTH TERMINAL. Energize the ME EQUIPMENT for these tests.

In the case of ME EQUIPMENT of CLASS II and ME EQUIPMENT with an INTERNAL ELECTRICAL POWER SOURCE, apply the test voltage between all LEAD WIRES, including the NEUTRAL ELECTRODE, connected together and the FUNCTIONAL EARTH TERMINAL and/or metal foil in close contact with the ENCLOSURE. Energize the ME EQUIPMENT for these tests.

ECG MONITORING EQUIPMENT having an INTERNAL ELECTRICAL POWER SOURCE, which is rechargeable from the SUPPLY MAINS, shall be tested with and without the SUPPLY MAINS connection if the ME EQUIPMENT is capable of operating while connected to SUPPLY MAINS.

Set the GAIN of the ME EQUIPMENT so such that a 5 mV signal produces a maximum display deflection without clipping the signal. With S2 closed and S3 opened, adjust the 10 Hz sine wave generator to produce a 5 mV peak-to-valley output signal. Open switch S2 and close S3.

Connect S1 to position A and charge the capacitor C. After about 10 s, connect S1 to position B. Leave in position B for 200 ms $\pm$ 50 %. Allow recovery to begin by opening S1 to remove residual voltages from the ME EQUIPMENT.

Immediately close S2 and open S3. Within 5 s, verify that the recorded test signal is not less than 80 % of the output before application.

Repeat the above test with the polarity of the high voltage source reversed. Repeat the tests with positive and negative polarities 5 times.

The ME EQUIPMENT shall resume normal operation in the previous operating mode, without loss of any OPERATOR settings or stored data within 5 s and shall continue to perform its intended function as specified in the ACCOMPANYING DOCUMENTS.

- **Differential mode test**

Addition:

Within 5 s after exposure to the defibrillation voltage, the ME EQUIPMENT shall resume normal operation in the previous operating mode, without loss of any OPERATOR settings or stored data, and shall continue to perform its intended function as described in the ACCOMPANYING DOCUMENTS.

ME EQUIPMENT having an INTERNAL ELECTRICAL POWER SOURCE which is rechargeable from the SUPPLY MAINS shall be tested with and without the SUPPLY MAINS connection if the ME EQUIPMENT is capable of operating while connected to the SUPPLY MAINS.

Compliance is checked by the following test:

The ME EQUIPMENT is connected to the test circuit shown in Figure 201.102. The test voltage is applied to each LEAD WIRE in turn with all the remaining LEAD WIRES being connected to earth. Initially, the test is conducted applying the test voltage between the L (LA) LEAD WIRE and all remaining LEAD WIRES connected to the N (RL) LEAD WIRE. The ME EQUIPMENT shall be energized for these tests.

Set the GAIN such that a 5 mV signal produces a maximum display deflection without clipping the signal. With S2 closed, adjust the 10 Hz sine wave generator to produce a 5 mV peak-to-valley output signal. Open switch S2.

Connect S1 to position A and charge the capacitor C. After about 10 s, connect S1 to position B. Leave in position B for 200 ms $\pm$ 50 %.

Open S1 in order to remove residual voltages from the ME EQUIPMENT and allow recovery to begin.

Immediately close S2. Within 5 s, verify that the recorded test signal is not less than 80 % of the output before application.

Repeat the test for any other LEAD WIRE according to Table 201.103 with all remaining LEAD WIRES connected to the N (RL) LEAD WIRE. The discharge test is applied at 20 s intervals in those cases where more than one discharge is indicated.

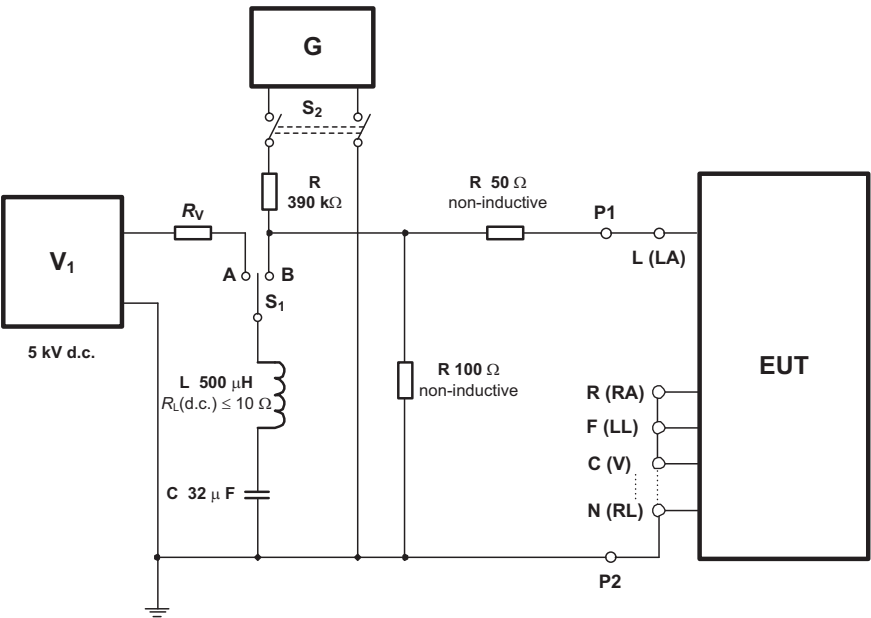
Table 201.103 – Protection against the effect of defibrillation (test conditions)

	P1	P2	LEAD setting	Number of tests
12 LEAD WIRES	L (LA)	R, F, N, C (RA, LL, RL, V)	I	1
	R (RA)	F, L, N, C (LL, LA, RL, V)	II	1
	F (LL)	L, R, N, C (LA, RA, RL, V)	III	1
	N (RL)	L, R, F, C (LA, RA, LL, V)	Standby	1
	C1 (V1)	L, R, F, N, C2-C6 (LA, RA, LL, RL, V2-V6)	V1	1
	C2 (V2)	L, R, F, N, C1, C3-C6 (LA, RA, LL, RL, V1, V3-V6)	V2	1
	C3 (V3)	L, R, F, N, C1, C2, C4-C6 (LA, RA, LL, RL, V1, V2, V4-V6)	V3	1
	C4 (V4)	L, R, F, N, C1-C3, C5-C6 (LA, RA, LL, RL, V1-V5, V5-V6)	V4	1
	C5 (V5)	L, R, F, N, C1-C4, C6 (LA, RA, LL, RL, V1-V4, V6)	V5	1
	C6 (V6)	L, R, F, N, C1-C5 (LA, RA, LL, RL, V1-V5)	V6	1
5 LEAD WIRES	L (LA)	R, F, N, C (RA, LL, RL, V)	I	1
	R (RA)	F, L, N, C (LL, LA, RL, V)	II	1
	F (LL)	L, R, N, C (LA, RA, RL, V)	III	1
	N (RL)	L, R, F, C (LA, RA, LL, V)	Standby	1
	C (V)	L, R, F, N (LA, RA, LL, RL)	V	1
3 LEAD WIRES	L (LA)	R, F, or N (RA, LL or RL)	I	2
	R (RA)	L, F, or N (LA, LL or RL)	I	2
	F (LL) or N (RL)	R, L (RA, LA)	II or standby	2
2 LEAD WIRES	L (LA)	R (RA)	I	1

NOTE1 The column 'number of tests' in Table 201.103 only applies to the defibrillation protection test. For other testing, the number of tests is one.

NOTE2 In the case of three LEAD WIRES there are configurations with a separate wire for the NEUTRAL ELECTRODE, and configurations without such separate wire. In the case of the former configuration the N (RL) is connected together with the respective R(RA), L(LA), or F(LL) wire to P2.

Additional to Figure 10:



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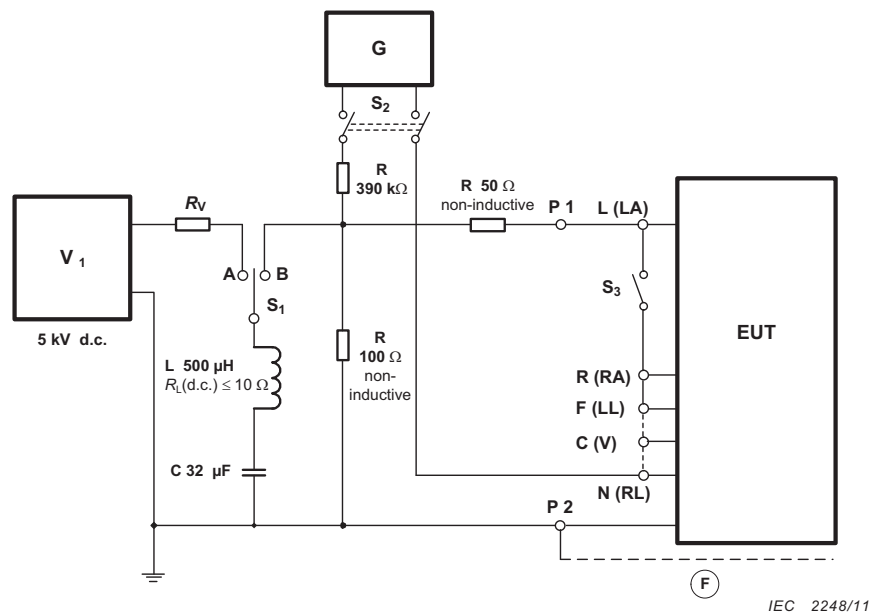
Components

- G Sine wave generator 20 V peak-to-valley of 10 Hz
- V_1 High voltage source 5 kV d.c.
- S_1 Switch; max. load 60 A, 5 kV
- S_2 Switch connecting the signal source, 5 kV
- R_L d.c. resistance of inductance L
- R_V Current limiting resistor
- P1, P2 Connecting points for EUT (includes PATIENT CABLES)

Test to be conducted with the MANUFACTURER'S recommended PATIENT CABLE and LEAD WIRES.

Figure 201.102 – Test of protection against the effects of defibrillation (differential mode)
(see 201.8.5.5.1)

Additional to Figure 9:



Components

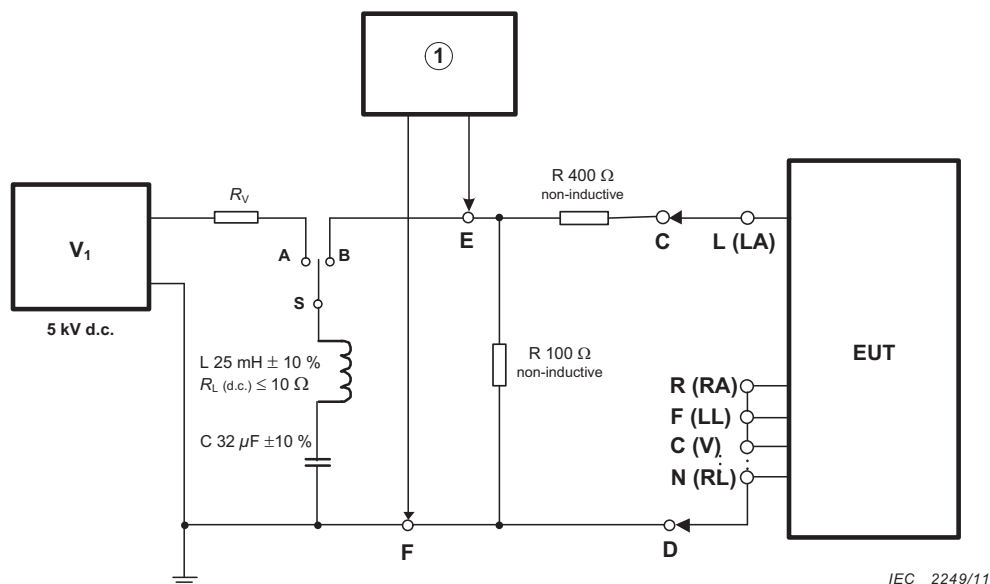
G	Sine wave generator 20 V peak-to-valley of 10 Hz
V ₁	High voltage source 5 kV d.c.
Ⓢ	Foil, simulating capacitance for CLASS II EQUIPMENT
S ₁	Switch; max. load 60 A, 5 kV
S ₂	Switch connecting the signal source, 5 kV
S ₃	Switch applying the signal source to LEAD WIRES
R _L	d.c. resistance of inductance L
R _V	Current limiting resistor
P1	Connecting point for EUT (includes PATIENT CABLES)
P2	Connecting point for FUNCTIONAL EARTH TERMINAL and/or metal foil in contact with ENCLOSURE

Test to be conducted with MANUFACTURER'S recommended PATIENT CABLE and LEAD WIRES.

Figure 201.103 – Test of protection against the effects of defibrillation (common mode)
(see 201.8.5.5.1)

201.8.5.5.2 Energy reduction test

Replacement of Figure 11:



Components

- ① Energy test equipment
- V_1 High voltage source 5 kV d.c.
- S Switch; max. load 60 A, 5 kV
- R_L d.c. resistance of inductance L
- R_V Current limiting resistor
- E, F Connecting points for energy test equipment
- C, D Connecting points for EUT (includes PATIENT CABLE)
(Energy test equipment can be a defibrillator tester)

Test to be conducted with the MANUFACTURER'S recommended PATIENT CABLE and LEAD WIRES.

Figure 201.104 – Application of the test voltage between LEAD WIRES to test the energy delivered by the defibrillator

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of the general standard applies.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of the general standard applies, except as follows:

201.12.1 Accuracy of controls and instruments

Addition:

201.12.1.101 ESSENTIAL PERFORMANCE and accuracy of ME EQUIPMENT

201.12.1.101.1 * Automated measurements on ECGS

If automated measurements are provided by the ELECTROCARDIOGRAPH, their accuracy shall meet the requirements as stated in this subclause.

201.12.1.101.2 * Requirements for amplitude measurements

If an ELECTROCARDIOGRAPH provides measurements, the accuracy of amplitude measurements shall be tested using the calibration and analytical ECGS of Table GG.1.

Feed 10 s of Table GG.1's calibration and analytical ECGS into the ELECTROCARDIOGRAPH under test (see guidelines for inputting ECGS in Clause AA.5). Determine the differences between the amplitude measurements and the reference values for LEADS I, II, V1, ..., V6 for all provided P-, Q-, R-, S-, ST- and T-waveforms.

If these ECGS are fed into the ELECTROCARDIOGRAPH in analogue format, perform this test five times. Calculate the differences between measurements and reference values of the five tests.

Exclude the two biggest differences in the amplitude measurements. The difference for each remaining amplitude measurement shall not deviate from the reference value by more than $\pm 25 \mu\text{V}$ for reference values $\leq 500 \mu\text{V}$, or by more than 5 % or $\pm 40 \mu\text{V}$ (whichever is greater) for reference values $> 500 \mu\text{V}$.

NOTE If the test ECG's are processed through the ELECTROCARDIOGRAPH'S high pass FILTERS before being processed by the measurement algorithm, a systematic difference of $\pm 20 \mu\text{V}$ is acceptable between the values of Appendix I and the measured values for the ST and T-wave amplitudes in records CAL20100, CAL20110, CAL20160, CAL20200, CAL20210 and CAL20260.

201.12.1.101.3 Requirements for interval measurements

The accuracy of the ECG REPORT'S measurements, if provided, shall be tested as follows.

201.12.1.101.3.1 * Requirements for absolute interval and wave duration measurements

The global interval and wave duration measurements of the calibration and analytical ECGS of Table GG.1 shall be used to evaluate the accuracy of absolute interval and wave duration measurements. Table 201.104 provides acceptable tolerances for the mean differences of global durations and intervals and Q-, R- and S-duration measurements.

Table 201.104 – Acceptable mean differences and standard deviations for global intervals and Q-, R-, S-durations on calibration and analytical ECGs

Measurement	Acceptable mean difference (ms)	Acceptable standard deviation (ms)
P-duration	±10	8
PQ-interval	±10	8
QRS-duration	±6	5
QT-interval	±12	10
Q-duration	±6	5
R-duration	±6	5
S-duration	±6	5

Feed the calibration and analytical ECGs listed in Table GG.1 into the ELECTROCARDIOGRAPH under test (simultaneous acquisition of all LEADS is assumed).

If these ECGs are fed into the ELECTROCARDIOGRAPH in analogue format, perform this test five times. Calculate the differences between the measurements and reference values of the five tests.

Compute the differences for each individual LEAD measurement (Q-, R-, and S-durations) for LEADS I, II, V1 ... V6 (if the wave is present) for all ECGs listed in Table GG.1. From the differences, remove the four largest deviations from the mean (outliers) for each measurement. The mean and standard deviation of the remaining differences shall not exceed the tolerances given in Table 201.104.

201.12.1.101.3.2 * Requirements for interval measurements on biological ECGs

Use the ECGs of Table GG.2 to evaluate the accuracy of interval measurements on biological ECGs.

Feed each of the 100 real test ECGs (MA1_ or MO1_ series from the CSE study, listed in Table GG.2) into the ELECTROCARDIOGRAPH under test in analogue or digital format and let them be analysed (see guidelines at the end of Annex AA for inputting ECGs). Determine the differences between the interval measurements and the reference values.

From the differences, remove the eight largest deviations from the mean (outliers) for each measurement. The mean and standard deviation of the remaining differences shall not exceed the tolerances given in Table 201.105.

Table 201.105 – Acceptable mean differences and standard deviations for global durations and intervals for biological ECGs

Global measurement	Acceptable mean difference (ms)	Acceptable standard deviation (ms)
P-duration	±10	15
PQ-interval	±10	10
QRS-duration	±10	10
QT-interval	±25	30

201.12.4 Protection against hazardous output

Additional subclauses:

201.12.4.101 * Indication of inoperable ELECTROCARDIOGRAPH

The ELECTROCARDIOGRAPH shall be provided with means to indicate that the ME EQUIPMENT is inoperable due to an overload or saturation of any part of the amplifier.

Compliance is checked by using the test circuit of Figure 201.106 to perform the following test:

Connect the signal generator between the R (RA) LEAD WIRE and all other LEAD WIRES connected to the N (RL) LEAD. In series with the signal generator, connect a d.c. power supply capable of providing a -5 V to +5 V output.

Adjust the signal generator to provide a 10 Hz signal. Apply a 10 Hz, 1 mV signal superimposed on a d.c. voltage variable from -5 V to +5 V.

Starting from zero, change the d.c. voltage in increments of 1 V steps from 0 V to 5 V and from 0 V to -5 V, using any baseline reset facility of the ELECTROCARDIOGRAPH to restore the trace.

The indicating device shall be fully operative before the amplitude of the 10 Hz signal is reduced to 5 mm (0,5 mV referred to the input).

201.12.4.102 LEADS**201.12.4.102.1 LEAD representation, nomenclature and definition**

In a rectangular coordinate system, increasing time is in the positive x-direction and the positive deflection of the trace is in the positive y-direction when a polarised d.c. signal is connected to the ELECTRODES. The nomenclature and definitions of Table 201.106 shall be used for the twelve standard LEADS and for the Frank LEADS.

Compliance is checked by measurement and inspection.

Table 201.106 – LEADS and their identification (nomenclature and definition)

Code 1 LEAD Nomenclature ^a	Definition ^b	Name of the LEAD
I	I = L-R (LA-RA)	Bipolar extremity LEADS (Limb LEADS Einthoven)
II	II = F-R (LL-RA)	
III	III = F-L (LL-LA)	
aVR	aVR = R-(L+F)/2 (RA-(LA+LL)/2)	Augmented LEADS Goldberger (From one of the ELECTRODES on the limbs to a reference point according to Goldberger)
aVL	aVL = L-(R+F)/2 (LA-(RA+LL)/2)	
aVF	aVF = F-(L+R)/2 (LL-(LA-RA)/2)	
V1	V1 = C1-CT (V1-CT)	Unipolar chest LEADS Wilson From one of the ELECTRODES on the chest to the central terminal according to Wilson (CT) CT= (L+R+F)/3
V2	V2 = C2-CT (V2-CT)	
V3	V3 = C3-CT (V3-CT)	
V4	V4 = C4-CT (V4-CT)	
V5	V5 = C5-CT (V5-CT)	
V6	V6 = C6-CT (V6-CT)	
Vx	Vx = 0,610A + 0,171C – 0,781I	Orthogonal vector LEADS (Frank LEADS, see Figure CC.1)
Vy	Vy = 0,655F + 0,345M – 1,000H	
Vz	Vz = 0,133A + 0,736M – 0,264I – 0,374E – 0,231C	
^a Other LEADS and their identifications are given in Annex CC.		
^b Definitions are given in terms of algebraic equations assuming that the ELECTRODE identifier represents the voltage sensed by the ELECTRODE with respect to a potential reference point. Table 201.102 defines the ELECTRODE identifiers.		

201.12.4.102.2 Minimum required configuration

The minimum LEAD-set is I, II, III, aVR or (-aVR), aVL, aVF, V1, V2, V3, V4, V5 and V6. It shall be possible for the OPERATOR to choose any combination of these LEADS for the ECG REPORT.

Compliance is checked by inspection.

201.12.4.102.3 Test of LEAD networks**201.12.4.102.3.1 General**

CENTRAL TERMINALS ACCORDING TO WILSON, Goldberger and Frank networks shall satisfy the following requirements for their effect on GAIN and their weighting factor accuracy. The networks shall not introduce a deviation in voltages of greater than 5 %.

201.12.4.102.3.2 Goldberger and Wilson LEADS

For Goldberger and Wilson networks, compliance shall be verified by the following test as appropriate to the ELECTROCARDIOGRAPH.

Feed CTS Test Atlas ECG waveforms CAL10000, CAL20000, CAL30000 and CAL50000 (see Annex HH) into the system. Measure the peak QRS amplitudes on the ECG REPORT and compare the measured values to the ones given in Annex HH or compare the measurement values generated by the ELECTROCARDIOGRAPH to the ones given in Annex HH. Make sure that the values measured do not deviate more than 10% from the nominal values.

201.12.4.102.4 Recovery time

When 300 mV d.c. is applied as a differential input voltage, the baseline shall return to within 3 mm of its initial position at NORMAL GAIN within 2 s after a LEAD switch.

At NORMAL GAIN and with LEAD III selected, apply 300 mV d.c. between R (RA) and all other LEAD ELECTRODES, including the NEUTRAL ELECTRODE, connected together (Fig. 201.106). More than 1 min after applying this voltage, switch to LEAD II and then LEAD aVR. The trace shall return to within 3 mm of the initial position within 2 s following each LEAD switch.

201.12.4.103 * Input impedance

The input impedance shall be at least 2,5 M Ω within a d.c. offset voltage range of ± 300 mV. This requirement does not apply to inputs used for measurements other than ECG (e.g. respiration).

Compliance is checked using the test circuit of Figure 201.106.

Open switch S1, close switches S and S2 and set S4 to position B. Connect the sine wave signal generator to any tested LEAD (P1 and P2) with all other LEAD WIRES connected to the N (RL) LEAD WIRE (P6) as defined in Table 201.104. Set the GAIN to 10 mm/mV and sweep speed to 25 mm/s. Adjust the sine wave generator to produce 80 % of full-scale peak-to-valley channel height on any display at a frequency of 0,67 Hz. Record the displayed output amplitude for this GAIN on the output display. Open S2 and set S4 to position A. Apply a d.c. offset voltage of +300 mV. The measured signal amplitude shall not decrease by more than 20 % on the output display. Repeat the test with a d.c. offset voltage of -300 mV. For d.c. offset voltages of +300 mV and -300 mV, repeat the test for a frequency of 40 Hz.

Repeat the above test for each LEAD WIRE until all combinations of LEAD WIRES have been tested as defined in Table 201.103.

Alternatively:

If the ELECTROCARDIOGRAPH, because of integrated signal processing, is not capable of handling sinusoidal signals for testing the calibration, feed CTS Test Atlas ECG CAL30000 (see Annex HH) into the system. Provide for every lead wire an impedance of 620 k Ω in parallel with 4.7 nF, and equipped with a switch S1.. Measure the amplitudes with S1 closed. Then repeat the measurement with S1 open. Ensure that the amplitudes do not decrease by more than 20 %..

201.12.4.104 Required GAINS

At least a GAIN of 10 mm/mV shall be provided for ECG REPORTS. If additional GAINS are provided, at least the GAINS of 5 mm/mV and/or 20 mm/mV shall be provided. The GAIN shall appear on the ECG REPORT.

Compliance is checked by inspection.

201.12.4.105 Reduction of the effects of unwanted external voltages**201.12.4.105.1 * COMMON MODE REJECTION**

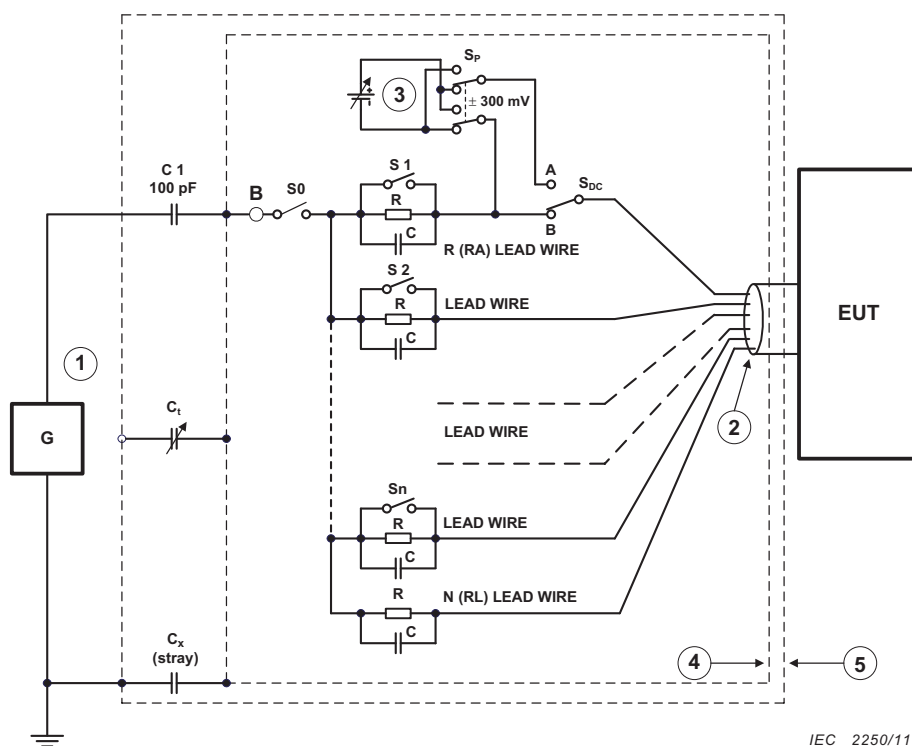
A 10 V r.m.s. signal at mains frequency with 200 pF source capacitance, connected between earth and all LEAD WIRES connected together shall not produce an output signal greater than 10 mm peak-to-valley at a GAIN setting of 10 mm/mV for not less than 15 s. In series with each ELECTRODE shall be a 51 k Ω resistor in parallel with a 47 nF capacitor. The PATIENT CABLE specified by the MANUFACTURER shall be used.

Compliance is checked using the test circuit of Figure 201.105 and a ruler or callipers accurate to within 0,2 mm. The test has to be performed with main frequencies of 50 Hz and 60 Hz.

- a) *Adjust C_t to produce 10 V r.m.s. at mains frequency at point B, while no PATIENT CABLE is attached (S0 open). The common mode voltage applied to the ME EQUIPMENT is then 10 V rms. Ensure that the line frequency notch filter (if provided) is turned off for this test, even if this requires special software or a special method of accessing the control over that filter.*
- b) *Close switches S0 and S2 through S_n , open S1, and set S_{DC} to position B. Set the GAIN to 10 mm/mV and the sweep speed to 25 mm/s. Measure the output amplitude for not less than 15 s period at that GAIN setting. Then open S2 and close all other switches. Repeat the amplitude measurement. Continue until the measurement has been made with all LEAD WIRES.*
- c) *Repeat the test with a +300 mV d.c. and –300 mV d.c. offset voltage in series with the imbalance impedance, by setting S_{DC} to position A and testing with switch S_P in each of its two positions.*

The resulting values shall not be greater than 10 mm peak-to-valley. Ensure that the line frequency notch filter (if provided) is turned off for this test, even if this requires special software or a special method of accessing the control over that filter.

In Figure 201.105 C_1 and C_t simulate the PATIENT'S capacitance to ground. The inner shield reduces the pickup of unwanted extraneous signals. Since the capacitance C_x between the inner and external shields influences both the source capacitance and the common mode voltage, this capacitance is increased by a trimmer capacitor to 100 pF, equal to the generator capacitor C_1 . The generator output is increased to 20 V_{rms}, thus providing 10 V_{rms} at the common mode point B with a source impedance equivalent to 200 pF when the PATIENT CABLE is not connected to the test circuit. The shield of the PATIENT CABLE must not be connected.



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Components

1	Signal generator 20 V _{rms} mains frequency
2	PATIENT CABLE
3	d.c. offset source
4	Inner shield
5	Outer shield
B	Common mode point
S ₁ -S _n	Switches; invoke unbalance circuit consisting of C and R
C	47 nF
R	51 kΩ
C _t	selectable capacitor
S ₀	Switch to energy source
S _{DC}	Switch to d.c. source

C1 and C_t simulate the PATIENT'S capacitance to ground. The inner shield reduces pickup of unwanted extraneous signals and eliminates the unbalance to ground. Since the capacitance C_x between the inner and outer shields influences both the source capacitance and the common mode voltage, a trimmer capacitor is used to increase this capacitance to 100 pF, equal to the generator capacitor C1. The generator output is increased to 20 V_{rms}, thus providing 10 V_{rms} at the common mode point B with a source impedance equivalent to 200 pF when the PATIENT CABLE is not connected to the test circuit.

Figure 201.105 – Test circuit for COMMON MODE REJECTION and NOISE level

201.12.4.105.2 * Overload tolerance

Differential input-circuit voltages of 1 V peak-to-valley shall not damage the ELECTROCARDIOGRAPH.

At normal GAIN (and with any switchable FILTER switched off) apply a differential input voltage of 1 V peak-to-valley to the LEAD ELECTRODES at any RATED SUPPLY MAINS frequency for 10 s. Ensure that the ELECTROCARDIOGRAPH'S recording system is not functionally damaged. Perform this test 3 times within a 5 min period. After the test, ensure that the ELECTROCARDIOGRAPH meets the requirements of clauses 201.12.4.103, 201.12.4.104 and 201.12.4.105.1 of this particular standard.

201.12.4.105.3 * FILTERS (including line frequency interference FILTERS)

Any OPERATOR adjustment to controls that degrades performance below this standard's defined ESSENTIAL PERFORMANCE shall, when activated, result in an indication on the ECG REPORT that clinical interpretation of the ECG REPORT may be affected by the FILTER settings.

Compliance is checked by inspection of the text printed on the ECG REPORT.

FILTERS for line frequency interference suppression shall not introduce on the ECG REPORT more than 50 μV peak-to-valley distortion of the signal in any LEAD when tested with the test ECG ANE20000.

Feed test ECG ANE20000 into the ELECTROCARDIOGRAPH at NORMAL GAIN without activating the line frequency interference FILTER and generate an ECG REPORT. Now activate the FILTER and generate a second ECG REPORT with the same ECG input of ANE20000.

Compliance is checked by comparing the peak NOISE measured in the ST segment on the two ECG REPORTS. The difference may not exceed 50 μV peak-to-valley.

201.12.4.106 Baseline**201.12.4.106.1 * NOISE level**

With the ELECTROCARDIOGRAPH set to the widest bandwidth for the resting ECG application, the line frequency notch FILTER if any, set to the appropriate mains frequency, and all other switchable FILTERS switched off, the NOISE level shall not exceed 30 μV peak-to-valley referred to the input over a 10 s period. This shall be done using the PATIENT CABLE specified by the MANUFACTURER and with all LEAD ELECTRODES connected to a common junction through a 51 k Ω resistor in parallel with a 47 nF capacitor in series with each LEAD WIRE.

Use the MANUFACTURER'S specified PATIENT CABLE(S) for the following test:

- a) *Insert in series with each LEAD WIRE of the PATIENT CABLE a 51 k Ω resistor in parallel with a 47 nF capacitor as shown in the test circuit of Figure 201.105*

(NOTE For this test all the switches S1 through Sn are open, S_{DC} is in position B, and the 20 V source G and the 100 pF capacitor are not connected (S0 open).

- b) *With the ELECTROCARDIOGRAPH set to its highest GAIN setting and widest bandwidth setting, and with the FILTERS set as previously stated, verify that the noise on the ECG REPORT is not greater than 30 μV peak-to-valley referred to input for a period of at least 10 s, for each position of the LEAD SELECTOR switch.*
- c) *Repeat this test nine more times. Verify that the 30 μV limit is not exceeded for at least nine of the 10 trials. The 10 trials shall occur within 30 min or less. The PATIENT CABLE and its connector shall be motionless during these tests. The PATIENT CABLE shall not be disconnected between trials.*