

INTERNATIONAL STANDARD

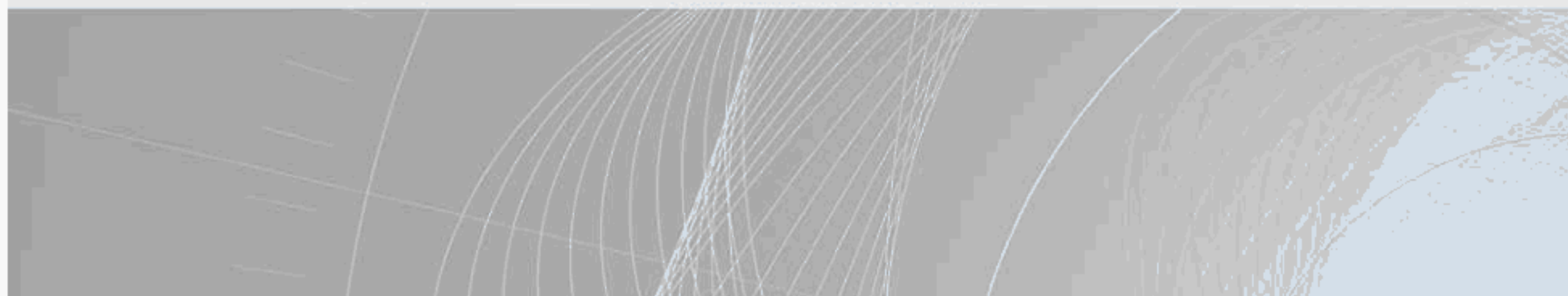
NORME INTERNATIONALE

Medical electrical equipment –

**Part 2-25: Particular requirements for the basic safety and essential performance
of electrocardiographs**

Appareils électromédicaux –

**Partie 2-25: Exigences particulières pour la sécurité de base et les performances
essentielles des électrocardiographes**





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IEC 60601-2-25

Edition 2.0 2011-10

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**Medical electrical equipment –
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Partie 2-25: Exigences particulières pour la sécurité de base et les performances
essentielles des électrocardiographes**

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –**Part 2-25: Particular requirements for the basic safety
and essential performance of electrocardiographs**

FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International standard IEC 60601-2-25 has been prepared by IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition of IEC 60601-2-25, published in 1993 and the first edition of IEC 60601-2-51, published in 2003. This second edition of IEC 60601-2-25 constitutes a technical revision of both those standards.

The text of this particular standard is based on the following documents:

FDIS	Report on voting
62D/944/FDIS	62D/957/RVD

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

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

In this standard, 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 standard, 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 standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, 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 standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “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.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site 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.

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.

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.

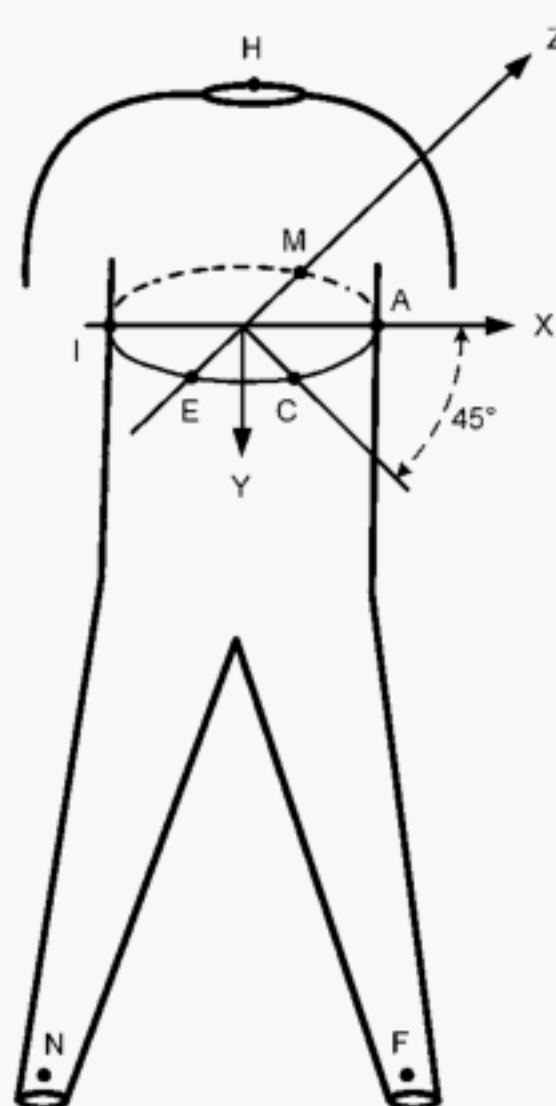
The PATIENT CABLE to ME EQUIPMENT connector shall be constructed or marked so that the OPERATOR can identify the ME EQUIPMENT to which the PATIENT CABLE should be connected.

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.

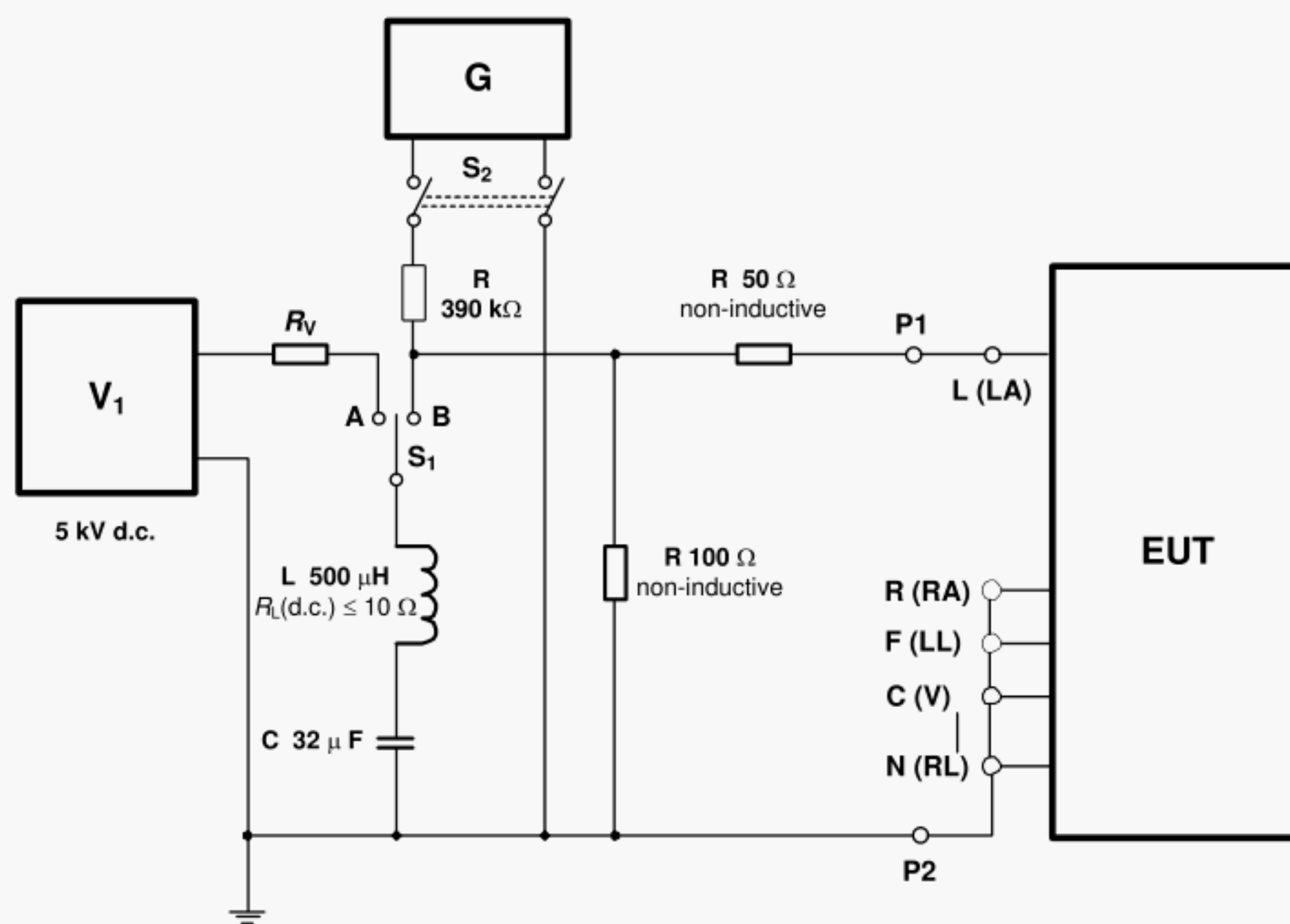
Table 201.103 – Protection against the effect of defibrillation (test conditions)

	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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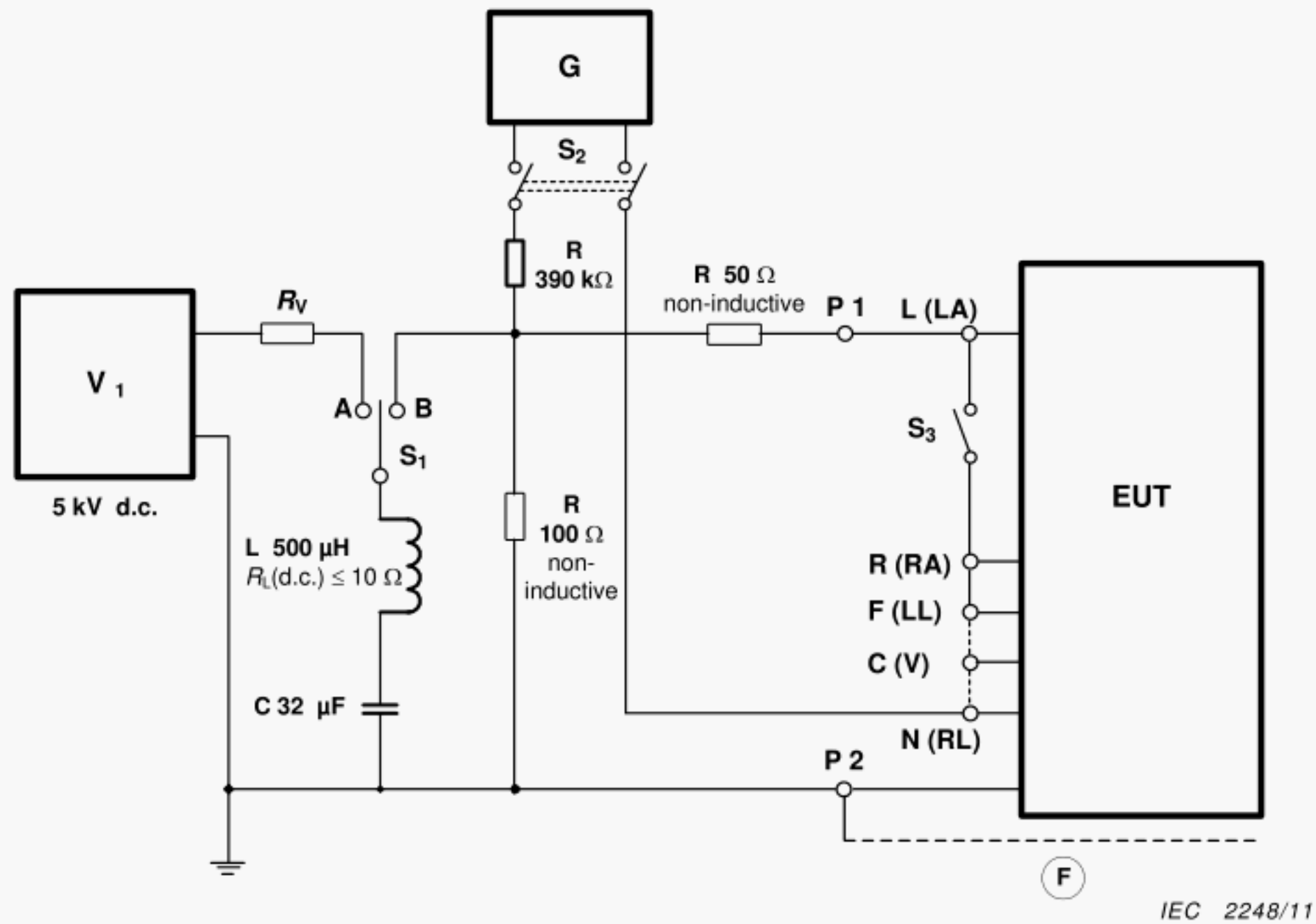
Components

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

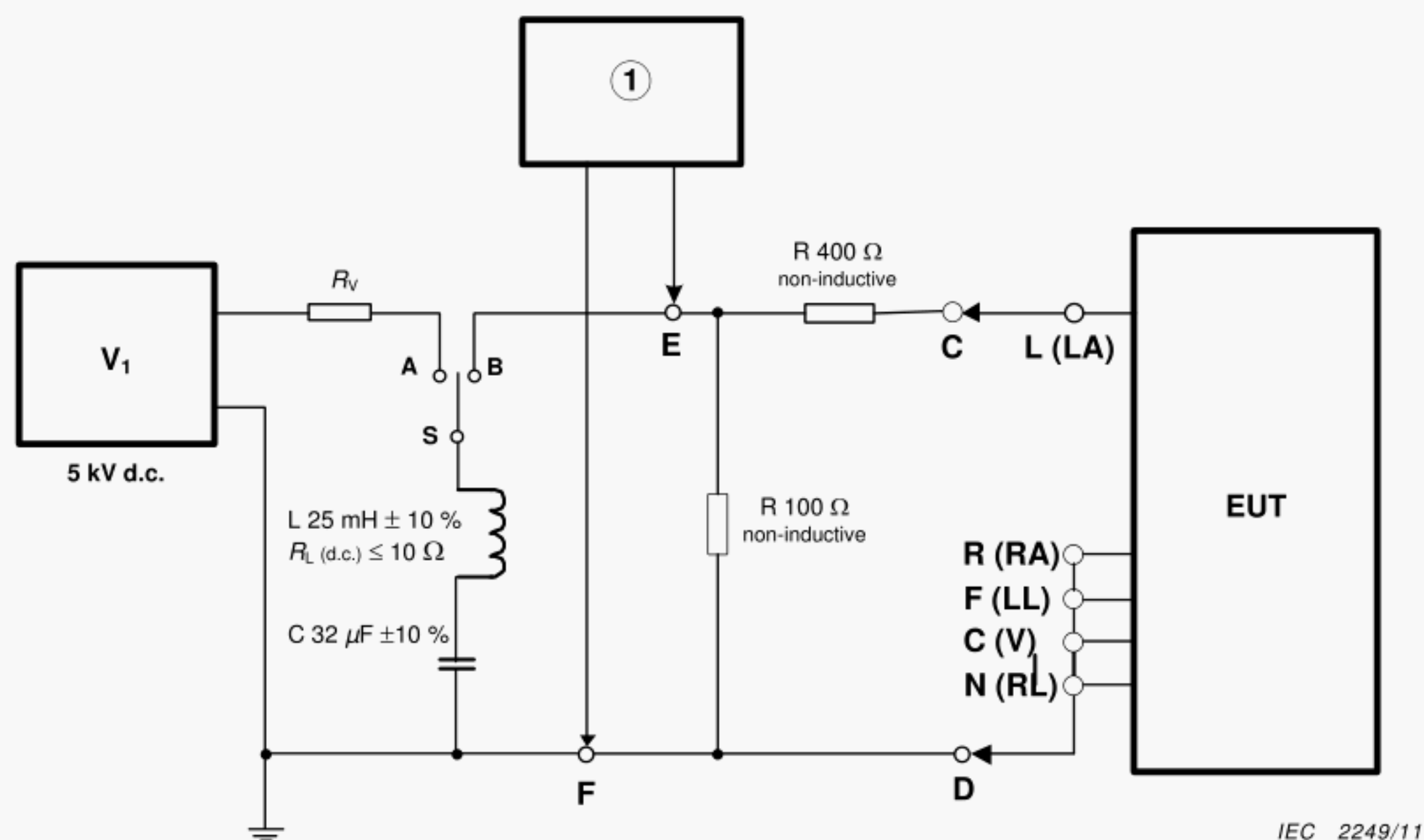
G	Sine wave generator 20 V peak-to-valley of 10 Hz
V ₁	High voltage source 5 kV d.c.
ⓕ	Foil, simulating capacitance for CLASS II EQUIPMENT
S ₁	Switch; max. load 60 A, 5 kV
S ₂	Switch connecting the signal source, 5 kV
S ₃	Switch applying the signal source to LEAD WIRES
R _L	d.c. resistance of inductance 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

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

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**

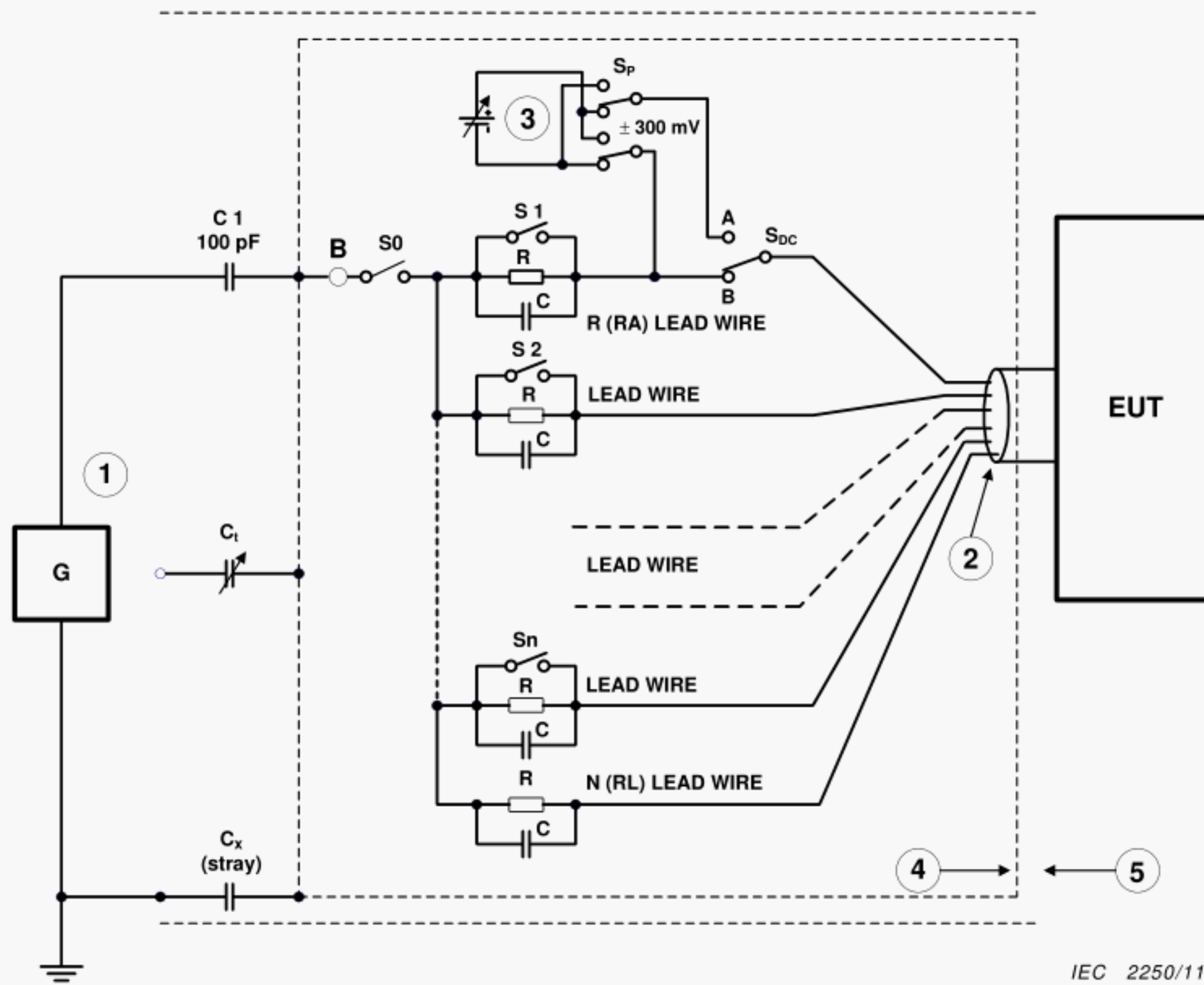
A 10 V r.m.s. signal at mains frequency with 200 pF source capacitance, connected between earth and all LEAD WIRES connected together shall not produce an output signal greater than 10 mm peak-to-valley at a GAIN setting of 10 mm/mV for not less than 15 s. In series with each ELECTRODE shall be a 51 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 (S_0 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 S_0 and S_2 through S_n , open S_1 , 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 S_2 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**

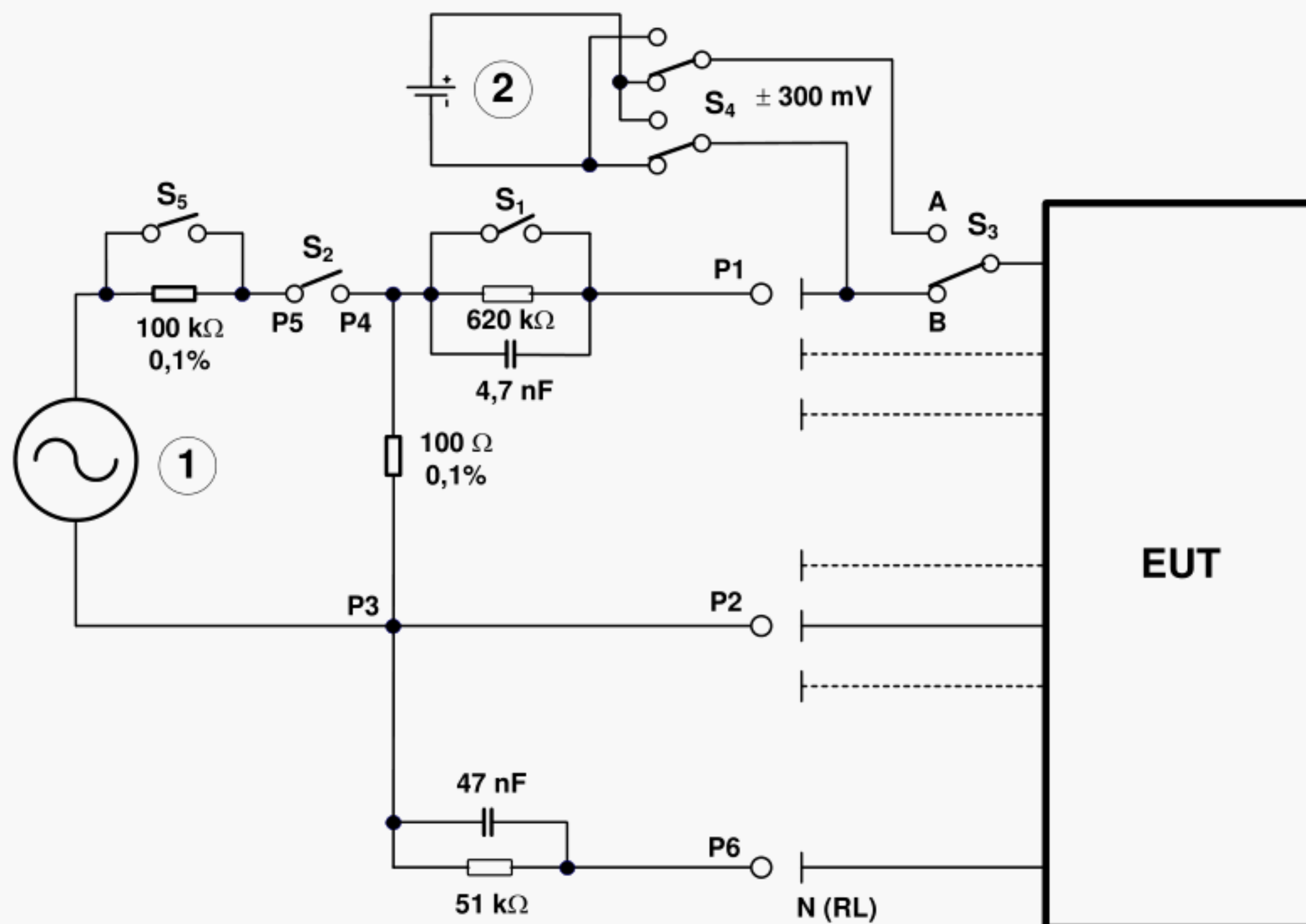
With the ELECTROCARDIOGRAPH set to the widest bandwidth for the resting ECG application, the line frequency notch FILTER if any, set to the appropriate mains frequency, and all other switchable FILTERS switched off, the NOISE level shall not exceed 30 μV peak-to-valley referred to the input over a 10 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.*



IEC 2251/11

Components

- 1 Signal generator; output impedance < 1 kΩ and linearity $\pm 1\%$
- 2 d.c. offset voltage source $\pm(\pm 300\text{ mV})$
- S_1 Switch, shorts unbalance caused by skin impedance
- S_2 Switch; disconnects the signal generator
- S_3 Switch, connects/disconnects the d.c. offset voltage source
- S_4 Switch, changes polarity of d.c. offset voltage source
- S_5 Switch; shorts the voltage divider
- P1,P2 Connecting points for LEAD WIRES
- P6 Connecting point for NEUTRAL ELECTRODE

Figure 201.106 – General test circuit

201.12.4.106.2 CHANNEL crosstalk

Input signals limited in amplitude and rate of change as per 201.12.4.107.2, applied to any one LEAD of a multichannel ELECTROCARDIOGRAPH and with all unused inputs connected to PATIENT reference through a 51 kΩ resistor in parallel with a 47 nF capacitor, shall not produce unwanted output greater than 2 % of the applied signals (multiplied by the gain) in those CHANNELS where no signal is applied.

Compliance is checked by the following test.

- a) Connect the multichannel ELECTROCARDIOGRAPH to the test circuit of Figure 201.106 with switches S_1 and S_2 closed, switch S_3 in position A, and PATIENT ELECTRODE connections F(LL), C1(V1), and, if provided, the Frank (E) joined to P1. Connect all unused PATIENT ELECTRODE connections via P2 to the NEUTRAL ELECTRODE through a parallel combination of a 51 kΩ resistor and a 47 nF capacitor.
- b) Adjust the signal generator to produce a 2,5 mV_{p-p}, 30-Hz triangular wave between P1 and P2.
- c) Operate the device at the NORMAL GAIN and time base, and record the outputs, which should display LEADS I, II, and III. The output of LEAD has to be less than 0,5 mm.
- d) Reconnect F(LL) from P1 to P2 and R(RA) from P2 to P1, and record the outputs which display LEADS I, II, and III. The output of LEAD III has to be less than 0,5 mm.

- e) Reconnect R(RA) from P1 to P2 and L(LA) from P2 to P1, and record the outputs. The output of LEAD II has to be less than 0,5 mm.
- f) Connect C1(V1) only to P1 and all other PATIENT ELECTRODE connections, via P2, to the reference LEAD through the parallel combination of 51 k Ω and 47 nF. Record the outputs of all CHANNELS. The output of all CHANNELS except that displaying V1 has to be less than 0,5 mm.
- g) Repeat (f) with C2(V2) through C6(V6) connected, in turn, to P1 and with all other PATIENT ELECTRODE connections connected to P2 as above. In each case, the output of all CHANNELS except the one displaying the LEAD connected to P1 has to be less than 0,5 mm.
- h) For Frank LEADS, the CHANNELS displaying X and Y outputs has to have outputs less than 0,5 mm.

201.12.4.107 Distortion

201.12.4.107.1 * Frequency response

ELECTROCARDIOGRAPHS shall exhibit a frequency response conforming to the specifications of 201.12.4.107.1.1 or 201.12.4.107.1.2 at NORMAL GAIN.

Compliance is checked by either 201.12.4.107.1.1 or 201.12.4.107.1.2.

201.12.4.107.1.1 Tests with sinusoidal and impulse signals

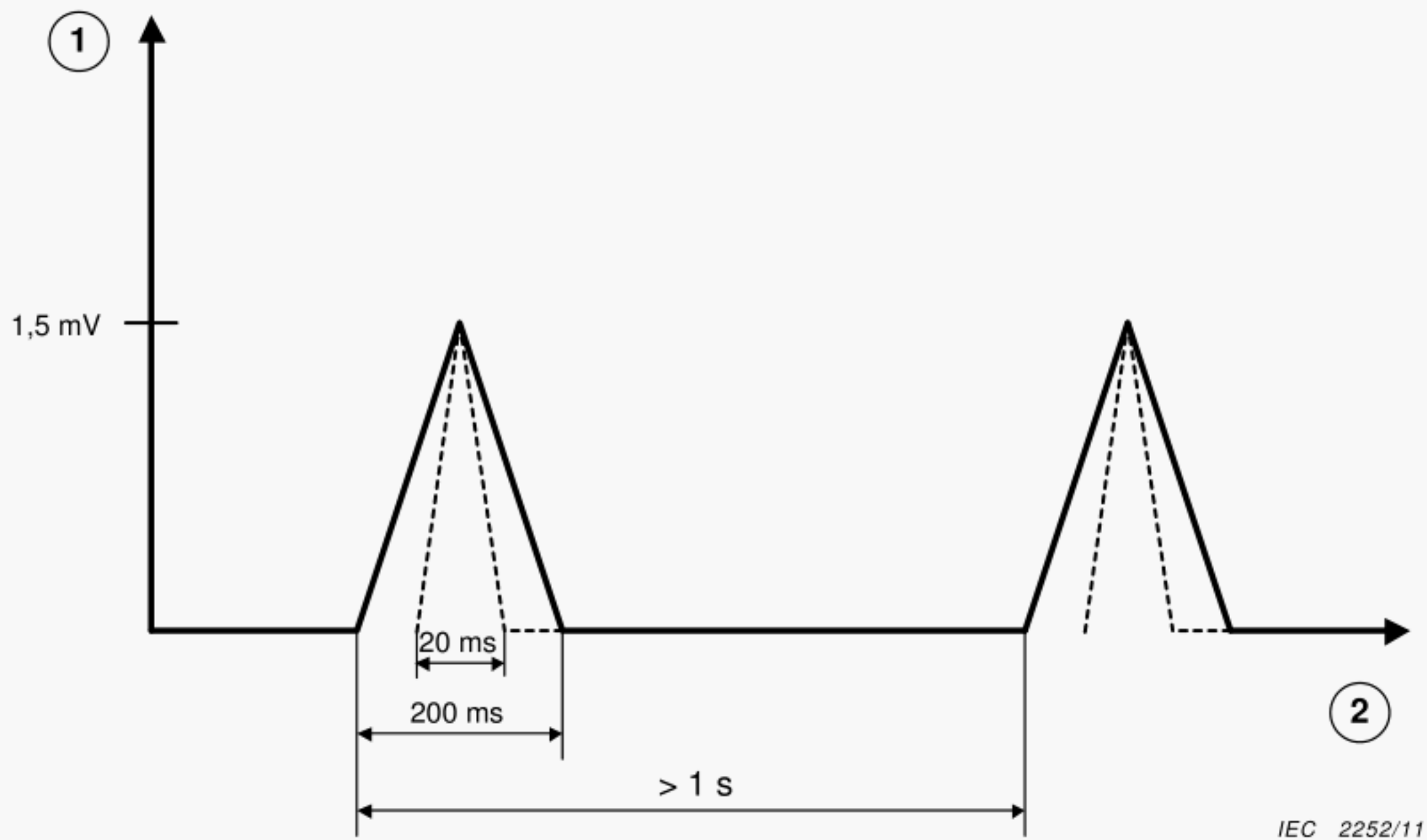
201.12.4.107.1.1.1 High frequency response

At NORMAL GAIN ELECTROCARDIOGRAPHS shall exhibit a high frequency response conforming to the specifications of Table 201.107.

The ELECTROCARDIOGRAPH has to meet the requirements of method A and E or alternately methods A, B, C and D of Table 201.107.

Table 201.107 – Frequency response

Test	Nominal input amplitude (mV _{p-v})	Input signal frequency and waveform	Relative output amplitude response on ECG REPORT
A	1,0	0,67 Hz to 40 Hz, sinusoidal	$\pm 10\%$ ^a
B	0,5	40 Hz to 100 Hz, sinusoidal	+10 % / –30 % ^a
C	0,25	100 Hz to 150 Hz, sinusoidal	+10 % / –30 % ^a
D	0,5	150 Hz to 500 Hz, sinusoidal	+10 % / –100 % ^a
E	1,5	≤ 1 Hz, triangular with 20 ms base width	+0 % / –10 % ^b
a Output amplitude relative to that for a 10 Hz sinusoidal input signal.			
b Output amplitude relative to that for triangular input with 200 ms base width (see Figure 201.107).			



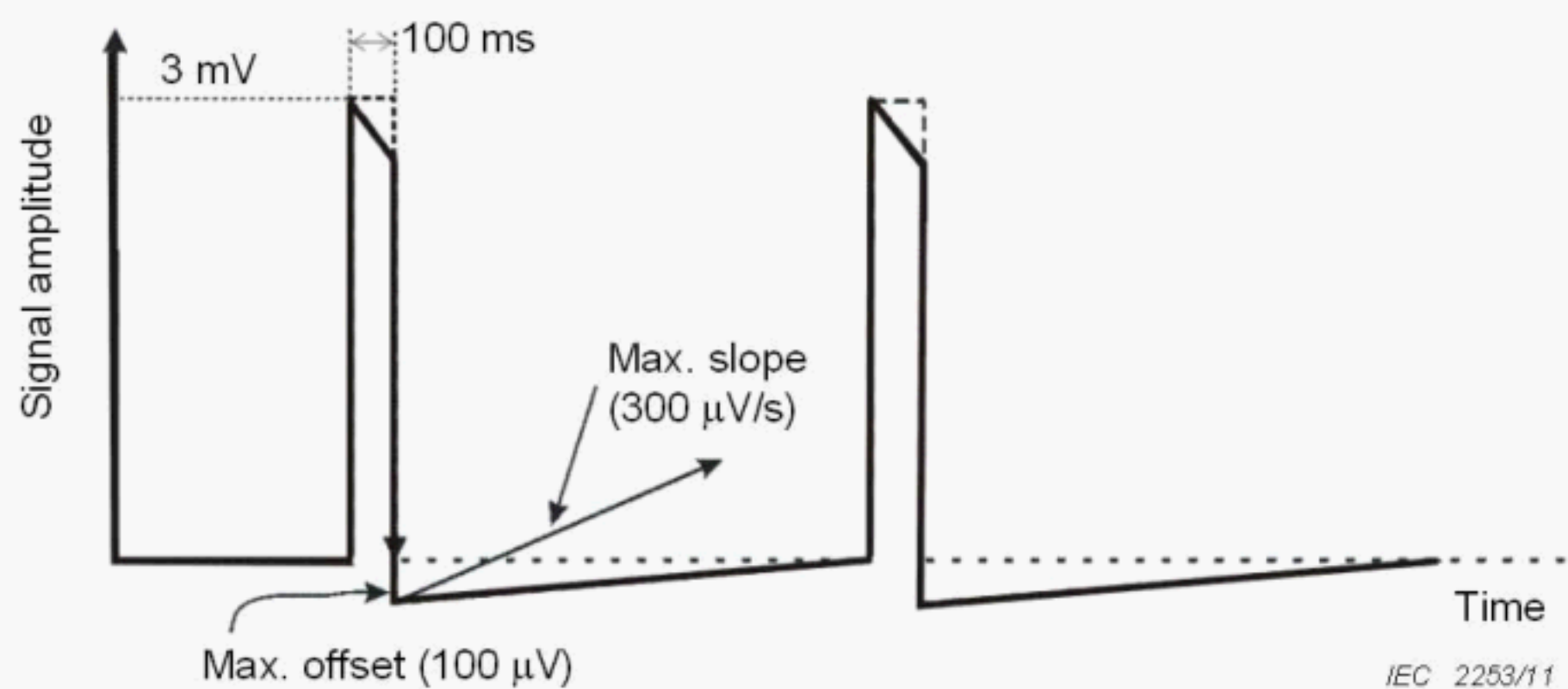
Key
 1 Signal amplitude
 2 Time

Figure 201.107 – Triangular waveforms for test E of Table 201.107

201.12.4.107.1.1.2 Low frequency (impulse) response

A $0,3 \text{ mV} \times \text{s}$ (3 mV for 100 ms) impulse input shall not produce a displacement greater than $0,1 \text{ mV}$ outside the region of the impulse.

For a $0,3 \text{ mV} \times \text{s}$ (3 mV for 100 ms) impulse input, the slope of the response must not exceed $0,30 \text{ mV/s}$ following the end of the impulse. See Figure 201.108. In ME EQUIPMENT which changes the a.c. coupling upon detection of a pacemaker pulse, disable the pacemaker pulse detection for this test.



Key
 ----- (dashed trace) Input impulse signal
 ————— (continuous trace) ELECTROCARDIOGRAPH response

Figure 201.108 – Input impulse signal and ELECTROCARDIOGRAPH response

201.12.4.107.1.2 Test with calibration ECGs

Alternatively, at NORMAL GAIN, the output peak amplitudes for R- and S-waves of recorded CALIBRATION ECGs shall not deviate by more than 5 % from the original values. ST amplitudes shall not deviate more than $\pm 25 \mu\text{V}$ from reference amplitude of the CALIBRATION ECG signal.

Feed CALIBRATION ECGs CAL20000, CAL20002, CAL20100, CAL20110, CAL20160, CAL20200 and CAL20500 into the ELECTROCARDIOGRAPH under test at NORMAL GAIN. On the ECG REPORT, verify that

- a) the R- and S-amplitudes do not deviate by more than 5 % from the reference amplitude of the respective CAL signal;*
- b) ST amplitude measurements taken between 20 ms and 80 ms after QRS-offset do not deviate by more than $25 \mu\text{V}$; ringing NOISE before and after the main deflection (QS, R, RS) has to be less than $25 \mu\text{V}$ peak; and the slope of the ST-segments does not exceed $0,05 \text{ mV/s}$.*

201.12.4.107.2 Linearity and dynamic range

The ELECTROCARDIOGRAPH shall be capable of recording a $\pm 5 \text{ mV}$ input signal (biphasic polarity applied to any LEAD).

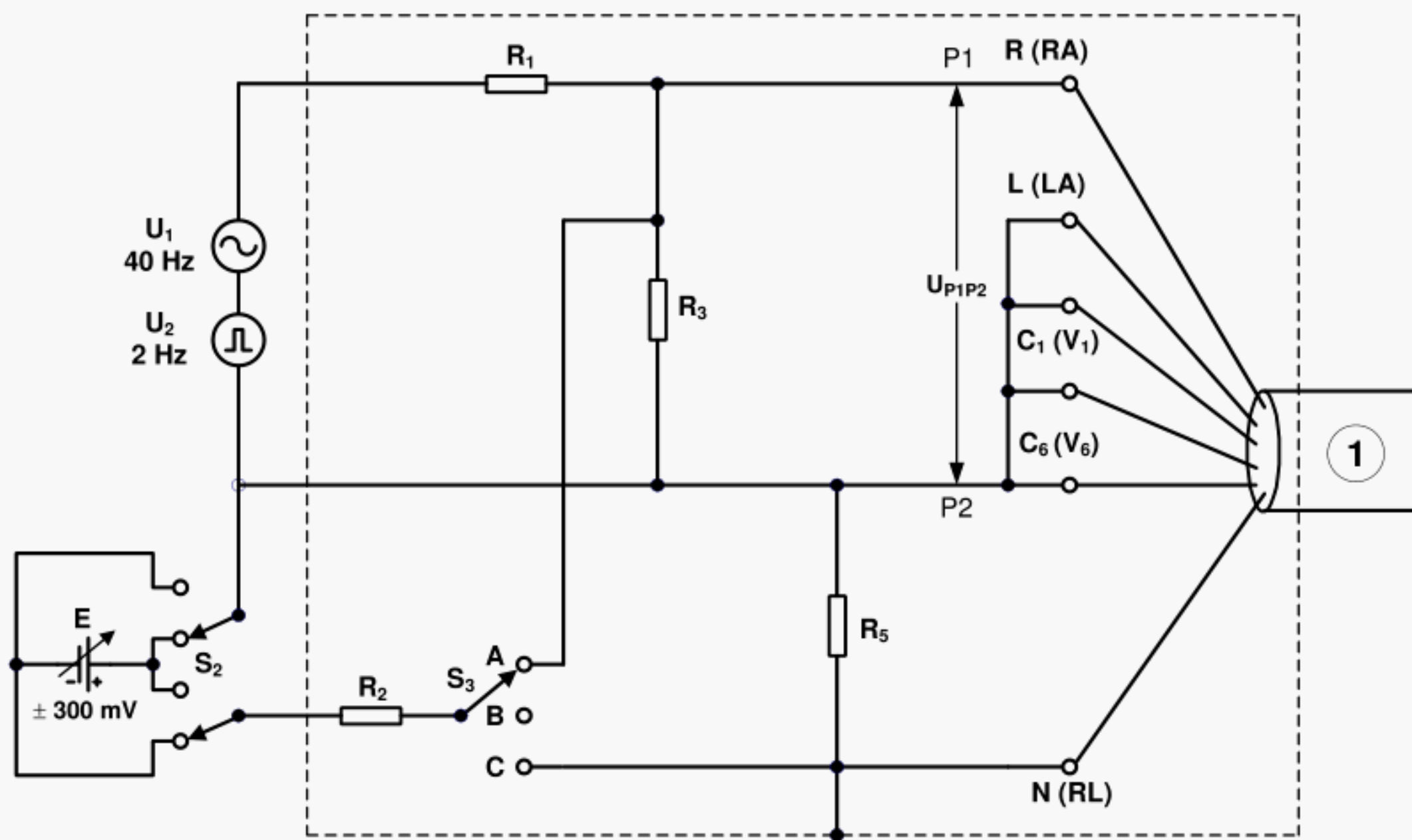
With an input signal producing a peak-to-valley deflection of 10 mV at the centre of the EFFECTIVE RECORDING WIDTH the recorded amplitude shall not change by more than 5 % ($\pm 500 \mu\text{V}$) when the recorded signal is shifted over the whole of the EFFECTIVE RECORDING WIDTH.

This requirement shall be met in the presence of differential and common mode DC OFFSET VOLTAGES of $\pm 300 \text{ mV}$. These offset voltages shall not be applied simultaneously.

Compliance is checked by one of the following two alternative test methods.

- a) Shift a sinusoidal signal at a frequency of 40 Hz (peak-to-valley deflection of 10 mV at the centre of the CHANNEL at minimum GAIN) over the whole of the EFFECTIVE RECORDING WIDTH by superimposing a variable amplitude square wave of approximately 2 Hz on the input signal (Figure 201.109 shows a respective test circuit). Ensure that the width of the deflection on the ECG REPORT, measured as indicated in Figure 201.110, in various positions does not deviate by more than $\pm 500 \mu\text{V}$.*
- b) Alternatively, instead of the sinusoidal 40 Hz signal, apply the CAL05000, CAL20000, and CAL50000 signals with an R to S difference amplitude of 1 mV , 4 mV , and 10 mV .*

Repeat the test in the presence of differential and common mode DC OFFSET VOLTAGES as specified in 201.12.4.103.1.



IEC 2254/11

The generators U1 and U2 shall have isolated outputs. The screening enclosure may be earthed.

Components

$R_1 = 100 \text{ k}\Omega$

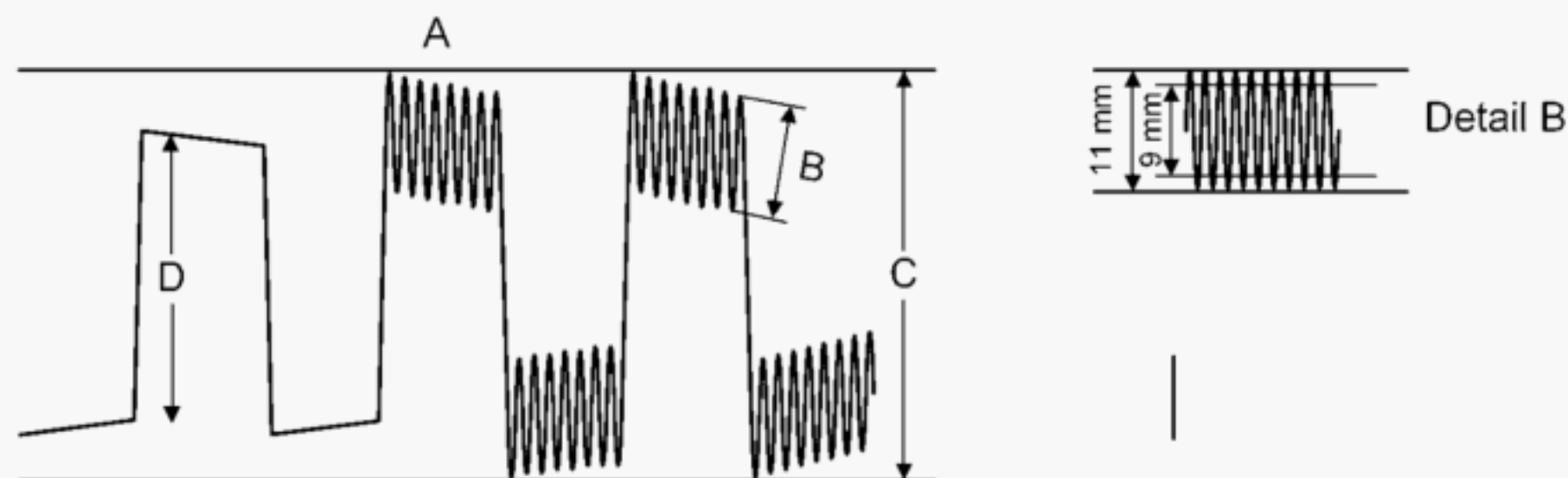
$R_2 = 4,7 \text{ k}\Omega$

$R_3 = 100 \text{ }\Omega$

$R_5 = 100 \text{ }\Omega$

1 PATIENT CABLE

Figure 201.109 – Circuit for test of linearity



IEC 2255/11

Key

A 40 Hz sine wave

B $10 \text{ mm} \pm 0,5 \text{ mm}$

C EFFECTIVE RECORDING WIDTH

D Amplitude of square wave signal

D is varied by changing the amplitude of U2 (see Figure 201.109).

Figure 201.110 – Result of linearity test

201.12.4.107.3 Sampling and amplitude quantisation during data acquisition

If uniform sampling of the ECG signals is employed, the ECG signals shall be sampled with at least 500 samples/s per CHANNEL during data acquisition. The skew between CHANNELS shall not be larger than $100 \text{ }\mu\text{s}$. Amplitude quantisation shall be $\leq 5 \text{ }\mu\text{V/LSB}$ referred to input.

A non-uniform sampling rate is permitted if equivalent performance can be demonstrated and if the sampling rate is at least 500 samples/s per CHANNEL within the QRS complexes.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

201.12.4.108 Printing, electronic storage and transmission

ELECTROCARDIOGRAPHS that are capable of printing, electronic storage and/or transmission of ECG REPORTS shall provide the capabilities as described in 201.12.4.108.1 and 201.12.4.108.2

NOTE In an emergency the PATIENT identification may not be readily available. In these cases the only means for identification are date and time of the recording.

201.12.4.108.1 Record identification

Each record shall include identifying information. This information shall be printed on the ECG REPORT as well as stored with the ECG data for further processing and transmission. The identifying information shall contain at least second, minute, hour, day, month and year of recording.

Compliance is checked by inspection of the identifying information.

201.12.4.108.2 PATIENT identification

The ELECTROCARDIOGRAPH shall provide means for PATIENT identification.

Compliance is checked by inspection of the identifying information.

201.12.4.108.3 ECG reporting on paper

201.12.4.108.3.1 Time and event markers

Time and/or event markers on the ECG REPORT shall not produce unwanted deflections greater than 0,5 mm in any CHANNEL at any GAIN. Time markers, if provided, shall be independent of the recording speed and shall be accurate to 2 % of the interval between successive time markers.

Test conditions are as specified in 201.12.4.107.3.

201.12.4.108.3.2 Recording speed

At least two recording speeds, 25 mm/s and 50 mm/s, shall be provided. The accuracy of these recording speeds shall not be worse than $\pm 5\%$ under the worst combinations of the conditions according to 5.3 of the general standard and to the addition to 201.5.3 in this particular standard.

Compliance is checked by using either of the following two test methods.

- a) *Verify compliance with recording speed selection requirements by visual inspection and operating of the recording speed selection mechanism of the ME EQUIPMENT. Verify recording speed accuracy by connecting a signal generator to any convenient rhythm LEAD of the ELECTROCARDIOGRAPH and adjusting the amplitude of a triangular signal so as to generate a 5 mm peak-to-valley signal on the ECG REPORT at $25 \text{ Hz} \pm 1\%$. At a recording speed of 25 mm/s and after not less than 1 s of running time, examine four consecutive sequences of 10 cycles each. Ensure that each sequence of 10 cycles occupies $10 \text{ mm} \pm 0,5 \text{ mm}$, measured without reference to the paper ruling and that the distance occupied on the ECG REPORT by 40 cycles is $40 \text{ mm} \pm 2 \text{ mm}$. Repeat the above test at 50 mm/s and recalculate all measured distances accordingly. The error must not exceed $\pm 5\%$.*
- b) *Alternatively (e.g. for ELECTROCARDIOGRAPHS with signal processing which cannot handle sinusoidal test signals), the accuracy of recording speed may be tested by applying a triangular test signal (triangle pulses $1 \text{ mV}/50 \text{ ms}$, repeat frequency $120/\text{min} = 500 \text{ ms} \pm 1\%$) or by feeding CALIBRATION ECG CAL20002 into the ELECTROCARDIOGRAPH. At a recording speed of 25 mm/s and after at least 6 s, examine eight consecutive pulse or cycle intervals on the ECG REPORT. Ensure that the eight intervals between any nine*

consecutive pulses/complexes occupy $100 \text{ mm} \pm 5 \text{ mm}$ without reference to the paper ruling. Repeat this test at a recording speed of 50 mm/s and recalculate all measured distances accordingly. The error must not exceed $\pm 5 \%$.

201.12.4.108.3.3 Time and amplitude ruling

Normal ruling shall be 1 mm , major ruling shall be 5 mm , with a tolerance of 2% .

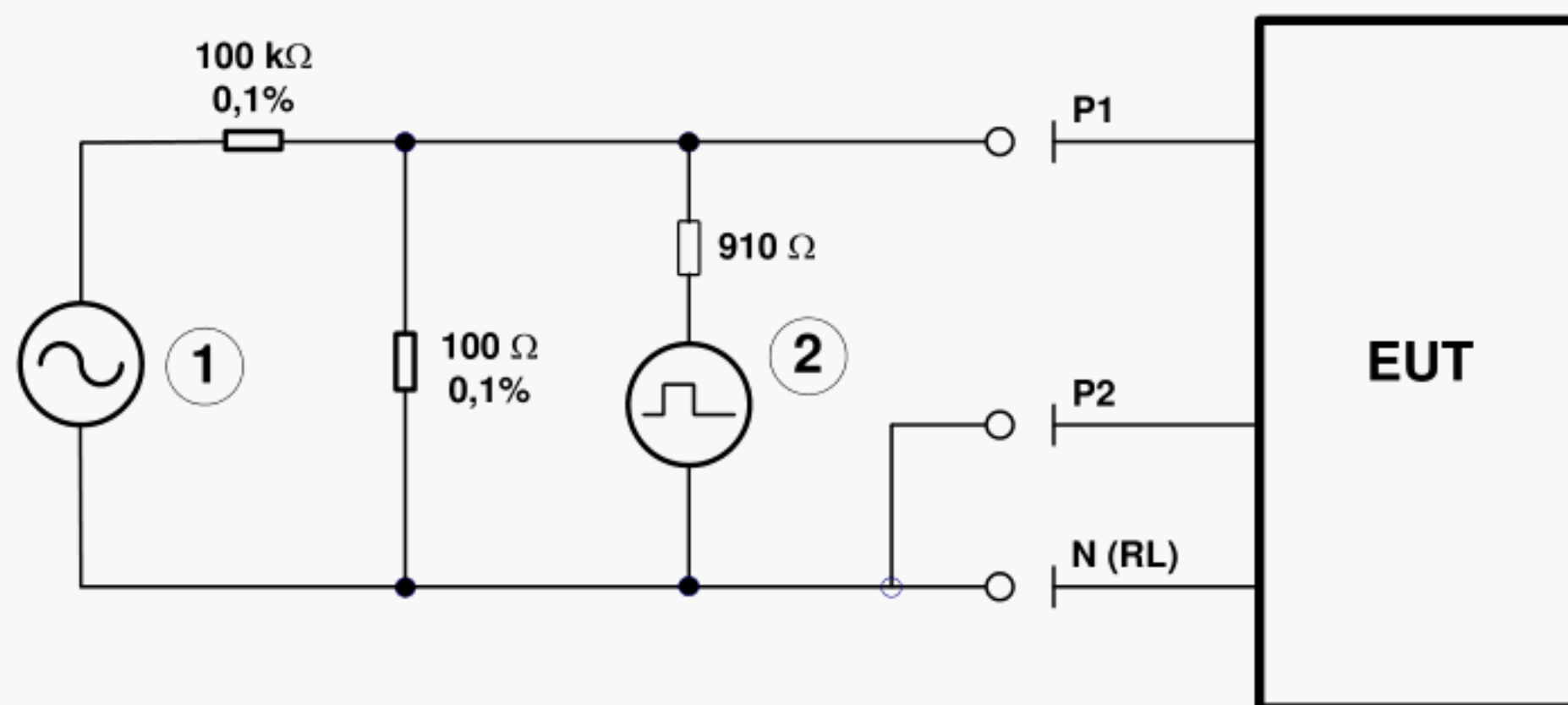
Compliance is checked by measurement.

201.12.4.109 Use with cardiac pacemakers

The ELECTROCARDIOGRAPH shall have the capability of displaying the ECG signal in the presence of pacemaker pulses with amplitudes between 2 mV and 250 mV , durations between $0,1 \text{ ms}$ and $2,0 \text{ ms}$, a rise time of less than $0,1 \text{ ms}$, and a frequency of 100 pulses per minute. For pacemaker pulses having durations between $0,5 \text{ ms}$ and $2,0 \text{ ms}$ (and amplitude, rise time and frequency parameters as specified above), an indication of the pacemaker pulse shall be visible on the report; this indication shall be visible on the display with an amplitude of at least $0,2 \text{ mV}$ referred to input.

Compliance is checked by the following method:

- a) Connect the ELECTROCARDIOGRAPH to Figure 201.111's test circuit, using the connections of Table 201.108 for each appropriate LEAD selection. Set the ELECTROCARDIOGRAPH to the standard recording conditions (GAIN 10 mm/mV ; time base 25 mm/s) and standard frequency response (or a higher one, if recommended by the manufacturer for pacemaker pulse display).



IEC 2256/11

Components

- 1 Signal generator; output impedance $< 1 \text{ k}\Omega$ and linearity $\pm 1 \%$; 1 V peak-to-valley, 40 Hz
- 2 Pacemaker pulse generator; pulse amplitude $2,5 \text{ V}$, duration 2 ms and frequency of $1,7 \text{ Hz}$

NOTE Adjust pulse amplitude and duration per step e).

Figure 201.111 – Pacemaker overload test circuit

Table 201.108 – PATIENT ELECTRODE connection for pacemaker pulse display test

Measuring lead	PATIENT ELECTRODE connection to P1	PATIENT ELECTRODE connection to P2
I	L (LA)	All others
II	R (RA)	All others
III	F (LL)	All others
V	C (V)	All others
Vi	Ci (Vi) (i = 1 to 6)	All others

- b) Adjust the sinusoidal generator to produce a 40 Hz, 10 mm peak-to-valley signal at the output of the ELECTROCARDIOGRAPH. Measure this amplitude.
- c) Adjust the pulse generator to add $250 \text{ mV} \pm 10 \text{ mV}$, $2 \text{ ms} \pm 0,2 \text{ ms}$ pulses to the PATIENT ELECTRODE connections. Ensure that these pulses have a frequency of 100 pulses per minute and a rise time of not greater than $100 \mu\text{s}$.
- d) 3 mm or 120 ms after each pacemaker pulse, measure the position of the top of the sinusoidal signal. This position must not differ by more than 1 mm from that measured 2 mm before the start of the pulse. Ensure that the peak-to-valley amplitude of the sinusoidal signal does not differ by more than ± 10 percent from the original value measured in step (b).
- e) Disconnect the sine wave generator (or reduce the output to 0,0 V). Adjust the pulse generator for a pulse width of $100 \text{ ms} \pm 10 \text{ ms}$, and adjust the output level to produce 20 mm, resulting in 2 mV at the input to the ELECTROCARDIOGRAPH. Reduce the pulse width to $0,5 \text{ ms} \pm 0,05 \text{ ms}$.
- f) Verify that the presence of the pulse is clearly visible, with an amplitude of at least 2 mm, and that during a 10 s period the baseline shift is less than $\pm 10 \text{ mm}$.
- g) Repeat (a) through (f) to test each appropriate LEAD selection.

Compliance is checked by measurement.

201.13 HAZARDOUS SITUATIONS and fault conditions

Clause 13 of the general standard applies.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard applies.

201.15 Construction of ME EQUIPMENT

Clause 15 of the general standard applies.

201.16 ME SYSTEMS

Clause 16 of the general standard applies.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Clause 17 of the general standard applies.

202 Electromagnetic compatibility – Requirements and tests

IEC 60601-1-2:2007 applies except as follows:

202.5.2.2.2 Requirements applicable to ME EQUIPMENT and ME SYSTEMS other than those specified for use only in a shielded location

Addition:

ELECTROCARDIOGRAPHIC EQUIPMENT and its ACCESSORIES shall not be considered LIFE-SUPPORTING ME EQUIPMENT.

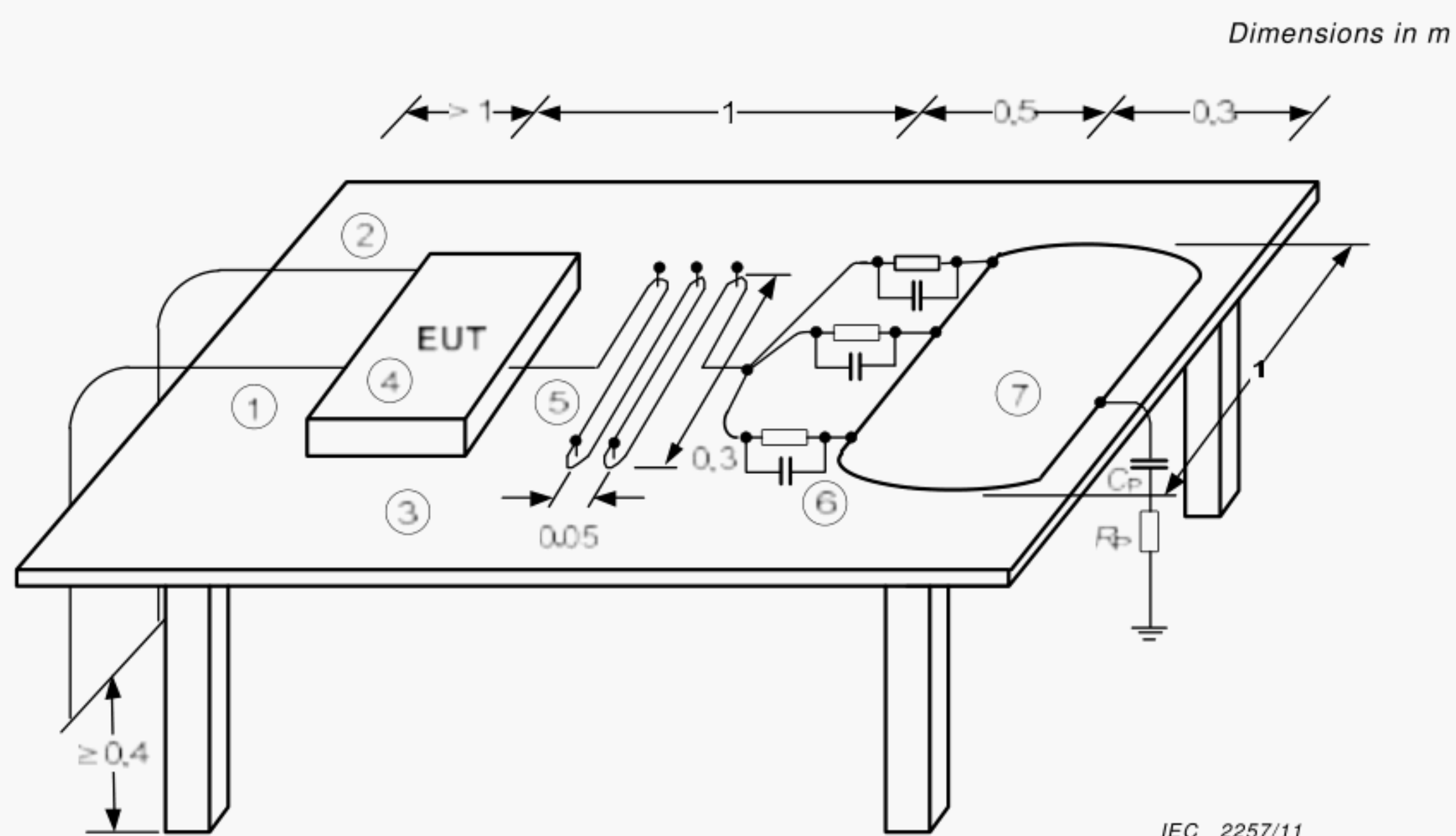
202.6.1 EMISSIONS

202.6.1.1.2 Tests

a) PATIENT CABLES

Replacement:

Test the ME EQUIPMENT with the PATIENT CABLE as specified by the MANUFACTURER with all SIP/SOP cables connected to ME EQUIPMENT (see Figure 202.101); ensure that the distances of SIP/SOP cables between the open end and floor (ground plane) are ≥ 40 cm.



Components

- 1 Mains cable
- 2 SIP/SOP cable
- 3 Table made of insulating material
- 4 ME EQUIPMENT under test
- 5 PATIENT CABLE
- 6 Load simulating the PATIENT (51 kΩ in parallel with 47 nF)
- 7 Metal plate
- C_p 220 pF
- R_p 510 Ω

C_p in series with R_p simulates the body of the PATIENT.

The RC network (C_p , R_p), the load simulating the PATIENT (6), and the metal plate (7) are not used during radiated emissions testing.

Figure 202.101 – Set-up for radiated and conducted emission test

202.6.2 IMMUNITY

202.6.2.1.10 *Compliance criteria

Addition:

The ME EQUIPMENT shall comply with the requirements of 201.12.1.101.2 when the signal CAL20110 of Table GG.1 is applied. The difference for each amplitude measurement shall not deviate from the reference value by more than $\pm 50 \mu\text{V}$ for reference values $\leq 500 \mu\text{V}$, or by more than 5 % or $\pm 100 \mu\text{V}$ (whichever is greater) for reference values $> 500 \mu\text{V}$.

202.6.2.2 ELECTROSTATIC DISCHARGE (ESD)

202.6.2.2.1 Requirements

Addition:

ME EQUIPMENT may show temporary DEGRADATION during discharges. Within 10 s 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 and maintain ESSENTIAL PERFORMANCE (see 202.6.2.1.10).

202.6.2.3 Radiated RF electromagnetic fields

202.6.2.3.1 Requirements

Addition to item a):

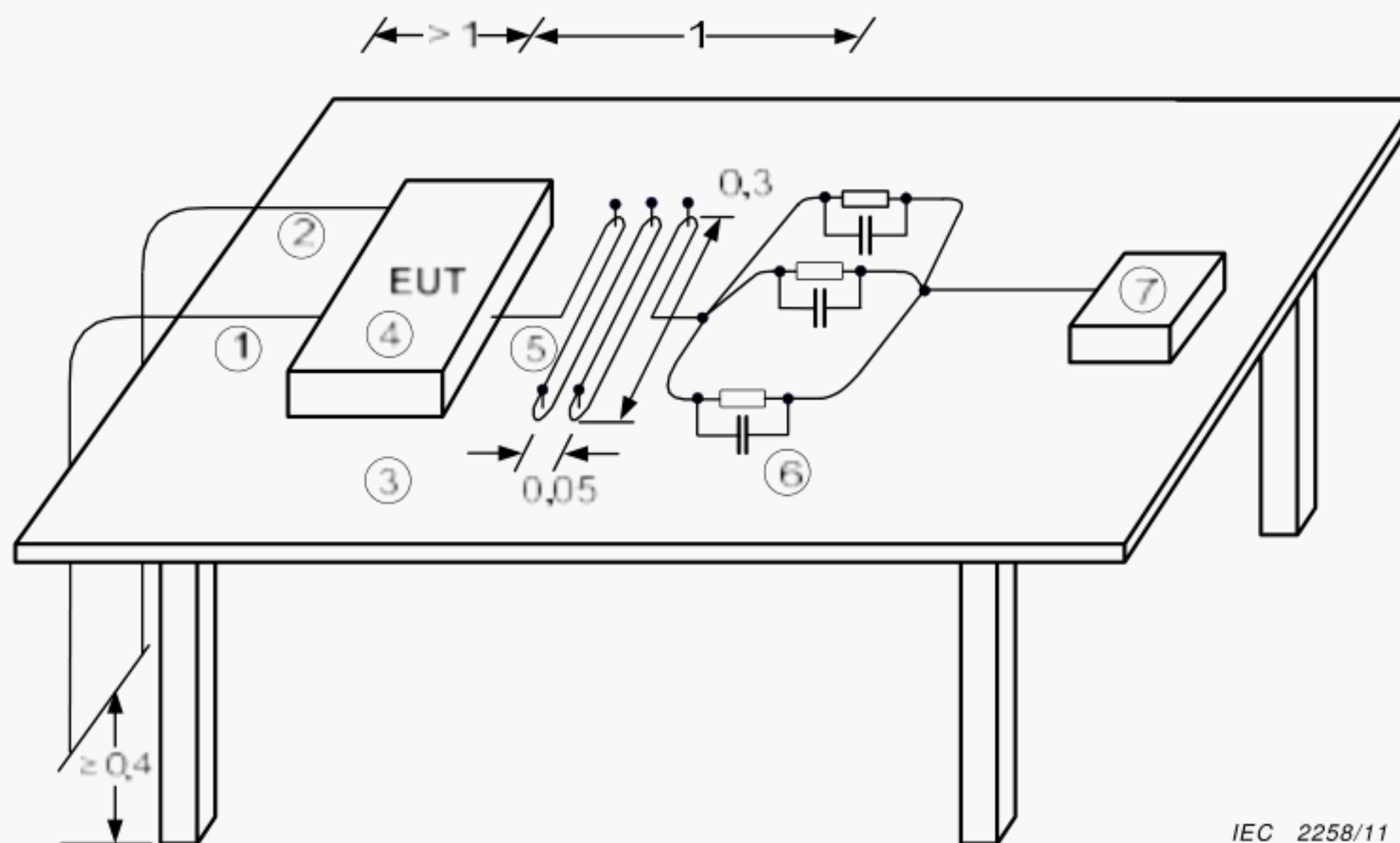
IMMUNITY TEST LEVELS of 3 V/m apply.

202.6.2.3.2 Tests

Addition:

- aa) Any SIGNAL INPUT/OUTPUT PART cable and POWER SUPPLY CORD are arranged generally as in Figure 202.102. Maintain distances of ≥ 40 cm between SIP/SOP cables and the floor (ground plane).
- bb) Perform the test using the simulated input signal as specified in subclause 202.6.2.1.10.

Dimensions in m



IEC 2258/11

Components

- | | |
|-------------------------------------|-----------------------------------------------------------------------------------------------------------------|
| 1 Mains cable | 5 PATIENT CABLE |
| 2 Signal cable | 6 Load simulating the PATIENT (51 k Ω in parallel with 47 nF) |
| 3 Table made of insulating material | 7 ECG simulator (shielded and, if necessary, low pass filtered, if susceptible to radio frequency interference) |
| 4 ME EQUIPMENT under test | |

Figure 202.102 – Set-up for radiated immunity test

202.6.2.4 Electrical fast transients and bursts

202.6.2.4.1 Requirements

Addition:

When exposed to electrical fast transients and bursts, via the POWER SUPPLY CORD, the ME EQUIPMENT shall continue to perform its intended function as described in this particular standard.

Testing of PATIENT CABLES and interconnecting cables specified to be more than 3 m in length may show temporary DEGRADATION during exposure to fast transients and bursts. Within 10 s 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. The ME EQUIPMENT shall comply with the requirements of 201.12.1.101.2 when the signal CAL20110 of Table GG.1 is applied.

202.6.2.4.2 Tests

Addition:

- aa) Position the ME EQUIPMENT $0,8\text{ m} \pm 0,08\text{ m}$ above the reference ground plane.*
- bb) Use the power cord provided with the ME EQUIPMENT to connect the ME EQUIPMENT to the output of EFT/B generator.*
- cc) Perform the test using the simulated input signal of requirements of 201.12.1.101.2 when the signal CAL20110 of Table GG.1 is applied.*

202.6.2.6 Conducted disturbances, induced by RF fields

202.6.2.6.1 Requirements

Addition:

- aa) When exposed to a conducted radio frequency voltage, via the POWER SUPPLY CORD, the ME EQUIPMENT shall continue to perform its intended function as described in the ACCOMPANYING DOCUMENTS. The ME EQUIPMENT shall comply with the requirements of 201.12.1.101.2 when the signal CAL20110 of Table GG.1 is applied. The difference for each amplitude measurement shall not deviate from the reference value by more than $\pm 50\text{ }\mu\text{V}$ for reference values $\leq 500\text{ }\mu\text{V}$, or by more than 5 % or $\pm 100\text{ }\mu\text{V}$ (whichever is greater) for reference values $> 500\text{ }\mu\text{V}$.*
- bb) PATIENT CABLES are exempt from this requirement.*

202.6.2.6.2 Tests

Addition:

- aa) Subclause 6.2.6.2, item c) and e) of IEC 60601-1-2:2007 do not apply for ME EQUIPMENT.*

Additional subclause:

202.6.2.101 * Electrosurgery interference

If the ME EQUIPMENT is intended to be used in an electrosurgery environment, a means shall be provided for protection against malfunction caused by electrosurgery. Perform the test below, using any PATIENT CABLES, LEAD WIRES, ACCESSORIES or settings recommended by the MANUFACTURER, applies.

When the ME EQUIPMENT is used together with HF SURGICAL ME EQUIPMENT it shall return to previous operating mode within 10 s after exposure to the field produced by the HF SURGICAL ME EQUIPMENT, without loss of any stored data.

Compliance is checked according to Figures 202.103 and 202.104.

Use the HF SURGICAL ME EQUIPMENT which complies with IEC 60601-2-2 and has a minimum power cut mode capability of 300 W, a minimum coagulation mode of 100 W and a working frequency of $400\text{ kHz} \pm 10\%$.

- a) Test in cut mode:*

Set the output power of the HF SURGICAL EQUIPMENT to the 300 W position.

Touch the metal contact/block in the test set-up (see Figures 202.103 and 202.104) with the active electrode and remove the electrode slowly to get an arc.

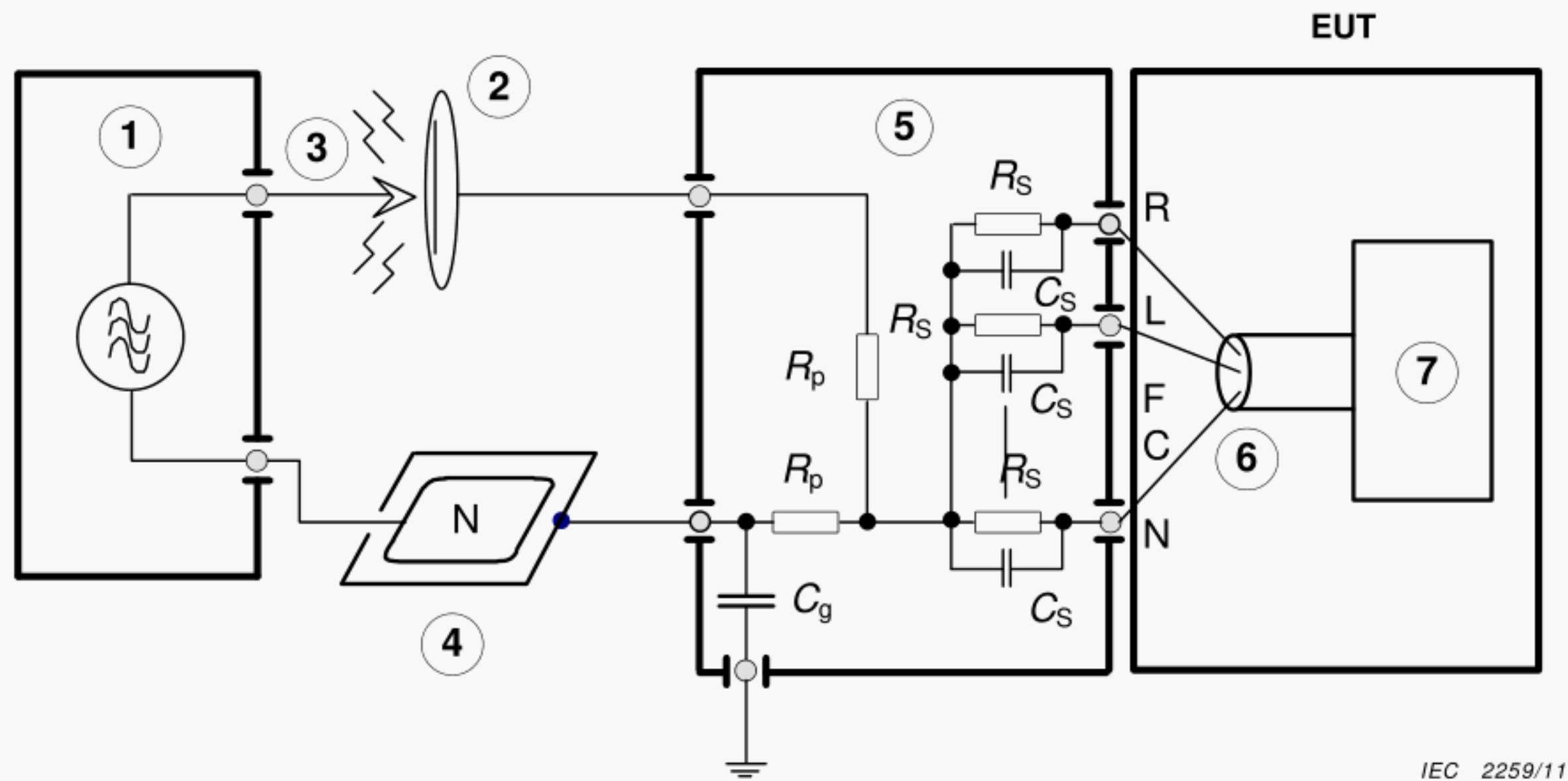
Verify whether the recorded/displayed ECG baseline returns within 10 s to its normal position and the ME EQUIPMENT returns to the previous operating mode without loss of any stored data.

Repeat the procedure five times.

b) Test in coagulation mode:

Repeat the test in item a) except with an output power of 100 W.

Test of the spray coagulation mode is excluded.



IEC 2259/11

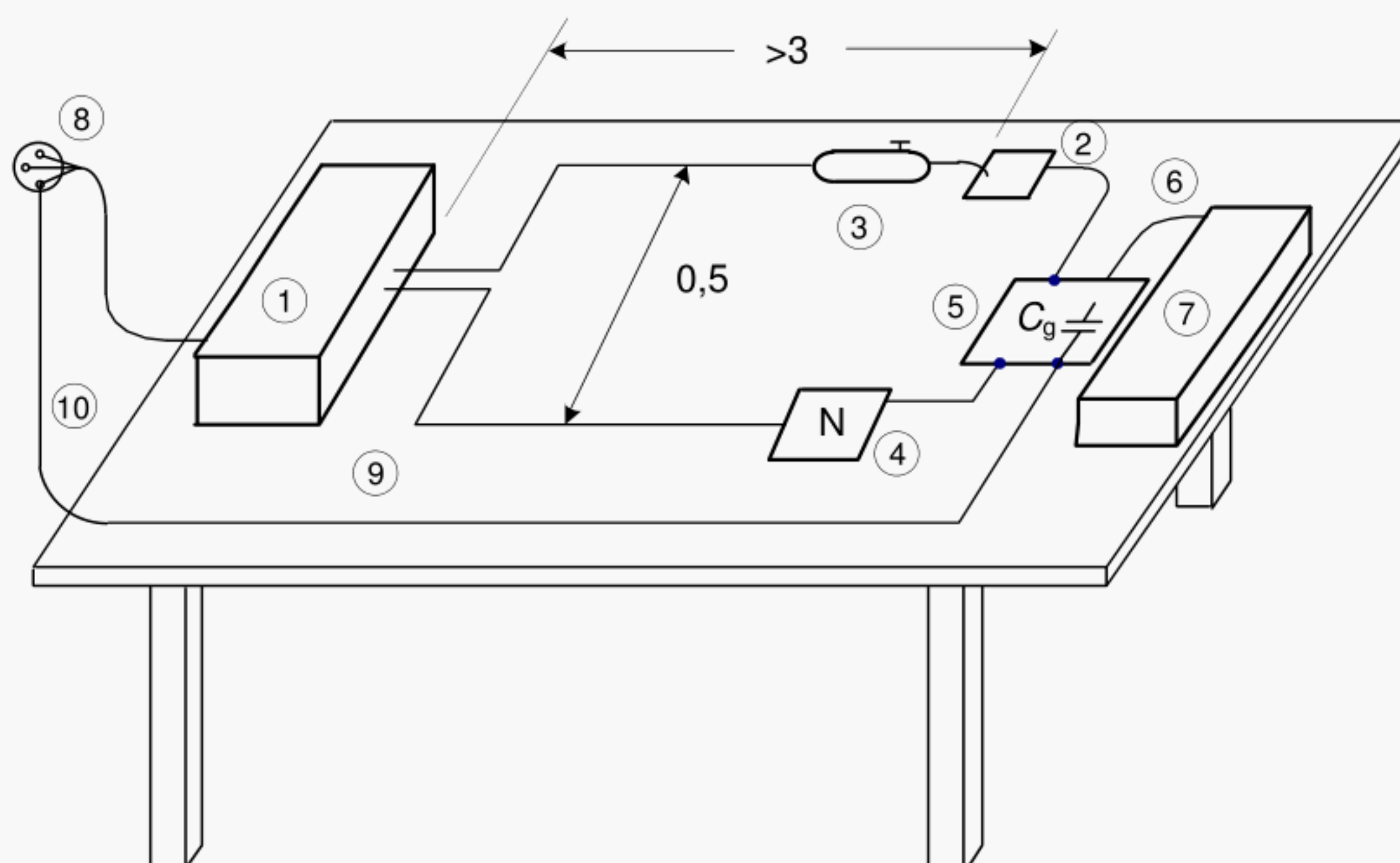
Components

- 1 HF SURGICAL EQUIPMENT
- 2 Metal plate
- 3 ACTIVE ELECTRODE of the HF SURGICAL EQUIPMENT
- 4 Metal plate/neutral electrode (N) of HF SURGICAL EQUIPMENT
- 5 Coupling network
- 6 PATIENT CABLE
- 7 ME EQUIPMENT
- R_p 500 Ω , 200 W (low-inductive, < 5 μ H, simulates PATIENT impedance)
- C_g 47 nF (to minimise the effect of different types of HF SURGICAL EQUIPMENT designs)
- R_s 51 k Ω $R_s//C_s$ simulate the skin impedance
- C_s 47 nF
- R, L, F, C, N LEAD WIRES according to Table 201.103

NOTE The test report should identify the HF SURGICAL EQUIPMENT that was used.

Figure 202.103 – Test circuit for HF surgery protection measurement

Dimensions in m



IEC 2260/11

Components

- 1 HF SURGICAL EQUIPMENT
- 2 Metal plate
- 3 ACTIVE ELECTRODE of the HF SURGICAL EQUIPMENT
- 4 NEUTRAL ELECTRODE of the HF SURGICAL EQUIPMENT
- 5 Coupling network – test set-up according to item 5 in Figure 202.103
- 6 PATIENT CABLE
- 7 ME EQUIPMENT under test
- 8 SUPPLY MAINS
- 9 Table made of insulating material
- 10 Connection to PROTECTIVE EARTH CONDUCTOR for grounding

Figure 202.104 – Test setup for HF surgery protection measurement**Annexes**

The annexes of the general standard apply, except as follows:

Additional annexes:

Annex AA (informative)

Particular guidance and rationale

AA.1 General considerations

ELECTROCARDIOGRAPH technology has evolved significantly from galvanometric designs to the current mostly digital designs. Although these newer designs often implement digital FILTERS, mixes of analogue and digital FILTERS may exist. Alternative test methods are provided for several requirements. The authors of this standard intend these two test methods to be equivalent, so an ELECTROCARDIOGRAPH only needs to pass one set of tests rather than both. Since these test methods do differ, a design may pass one test but fail the alternative test by a small margin. Manufacturers should, therefore, identify which test method should be used so that testing bodies only perform a single test.

Some requirements require disclosure of performance information in ACCOMPANYING DOCUMENTS. The intent is to make this information readily available to customers who want it, rather than to expand the INSTRUCTIONS FOR USE. This may be disclosed in any document that the ELECTROCARDIOGRAPH MANUFACTURER makes generally available (e.g., physician's guides, technical notes, or INSTRUCTIONS FOR USE).

AA.2 Guidance and rationale for particular subclauses

Subclause 201.1.1 – Scope

The scope of this particular standard is so defined as to include ELECTROCARDIOGRAPHS most commonly used for acquiring an ELECTROCARDIOGRAM from a PATIENT. The output of these ELECTROCARDIOGRAPHS, an ECG REPORT, is used to derive a diagnosis, i.e. primarily determine the state of the PATIENT'S heart, taking into account the rhythm characteristics as well as the morphological characteristics of the ELECTROCARDIOGRAPHIC signal.

The scope excludes a number of special types of ELECTROCARDIOGRAPHS which require further study before minimum requirements for safety can be established. However, in the absence of particular standards for these categories of ME EQUIPMENT, this standard could usefully serve as a guide to the appropriate requirements for BASIC SAFETY and ESSENTIAL PERFORMANCE.

Subclause 201.5.3 – Ambient temperature, humidity, atmospheric pressure

An extended range for humidity is required since ELECTROCARDIOGRAPHS may be used outside medically used rooms. The requirements specified are intended to cover the majority of environmental conditions likely to be encountered in practical use.

Subclause 201.5.8 – Sequence of tests

The defibrillation protection test has to be carried out before the leakage current and dielectric strength test to ascertain, that the leakage current and dielectric strength performance has not been degraded.

Subclause 201.7.4.101 – PATIENT CABLE and PATIENT CABLE to ME EQUIPMENT connector

This standard allows two possible colour codes for identifying each ELECTRODE. This is because one colour code is accepted in the USA and the other code in Europe and the rest of the world.

In Table 201.102, the use of “V” in Code 2 (usually American) is confusingly used for both an ELECTRODE identifier and a LEAD name. Since this reflects current practice, there is no easy solution to this double meaning.

Subclause 201.7.9.2.101 a) 14) – Additional instructions for use

This requirement covers both frequent (daily) checks by the clinician to detect mechanical damage and damage to cables etc as well as less frequent, but more comprehensive, technical checks.

Subclause 201.8.5.5.1 – Defibrillation protection

ELECTROCARDIOGRAPHS are generally only connected to PATIENTS for brief diagnostic procedures, so from a temporal point of view, the probability of simultaneous defibrillator use is low. Additionally, as an early diagnostic tool, being connected to an ELECTROCARDIOGRAPH does not necessarily mean that the PATIENT has a cardiac condition.

When these two events (a diagnostic ECG procedure and defibrillator use) coincide, the ELECTRODES, LEADS and ELECTROCARDIOGRAPH receive a considerable portion of the effective defibrillator voltage. The ELECTROCARDIOGRAPH may then be used to determine the PATIENT'S condition. The likelihood of these devices being used together is, therefore, greater than it first appears.

This led the Working Group to conclude that defibrillator protection is required for ELECTROCARDIOGRAPHS since they must show a reasonable trace within a few seconds to allow the OPERATOR to determine whether defibrillation was successful. Subclause 201.8.5.5.1's requirement for system recovery within 5 s of the defibrillation action ensures a visible trace is available.

When a defibrillation voltage is applied to the thorax of a PATIENT via externally applied paddles, the body tissue of the PATIENT in the vicinity of the paddles and between them becomes a voltage dividing system.

The voltage distribution can be gauged roughly using three-dimensional field theory but is modified by local tissue conductivity which is far from uniform.

If the ELECTRODE of an item of ME EQUIPMENT is applied to the thorax or trunk of the PATIENT, roughly within the compass of the defibrillator paddles, the voltage to which such an ELECTRODE is subjected depends on its position but will generally be less than the on-load defibrillator voltage.

Unfortunately it is not possible to say how much less as the ELECTRODE in question may be placed anywhere in this area, including immediately adjacent to one of the defibrillator paddles. For safety, therefore, such an ELECTRODE and ME EQUIPMENT to which it is connected has to withstand the full defibrillator voltage, and this needs to be the no-load voltage as one of the defibrillator paddles may not be making good contact with the PATIENT.

Only in special cases where the ELECTRODES are known with certainty to be placed either almost exactly between the defibrillator paddles (such as oesophageal ELECTRODES) or, electrically, effectively between them but at a remote point on the PATIENT (such as ECG or urological ELECTRODES), can it be safely assumed that the voltage applied to the ELECTRODE will be less than the voltage of the defibrillator. In such cases, a safe requirement for the ELECTRODES and ME EQUIPMENT to which they are connected is that they need to be able to withstand somewhat over half the no-load voltage of the defibrillator.

The last set of circumstances to be considered is when the ELECTRODE is connected to the PATIENT outside the compass of the defibrillator paddles, such as on the PATIENT'S arm or shoulder. The only safe assumption here is that no voltage dividing effect takes place, and the

arm or shoulder becomes effectively an open-ended electrical conductor connected to the nearer defibrillator paddle. The ELECTRODE and associated ME EQUIPMENT in such cases have to withstand the full no-load voltage of the defibrillator.

In this discussion, as in the requirements of the particular standards, it is assumed that one or the other of the defibrillator paddles is earthed.

Table AA.1 – ELECTRODE positions and electrical strength requirements

ELECTRODE position	Electrical strength requirement
On or in thorax, exact position indeterminate	Full no-load defibrillator voltage: 5 kV
On or in thorax or remote from it, but predictably electrically midway between defibrillator paddles	Somewhat over half no-load defibrillator voltage: 3 kV
Remote from thorax, not electrically midway between defibrillator paddles	Full no-load defibrillator voltage: 5 kV

In the case of this particular standard for the safety of ELECTROCARDIOGRAPHS, the first and third of the above conditions apply as both chest and limb ELECTRODES are used in diagnostic procedures according to the LEAD position.

ELECTROCARDIOGRAPHS shall, therefore, be subjected to a test voltage of 5 kV.

In order that the success or failure of an attempt to defibrillate a PATIENT may be determined as soon as possible, a rapid recovery is necessary from the amplifier overload produced by the pulse.

The test circuits of Figures 201.102 and 201.103 include a 50 Ω current-limiting resistor, which represents the resistance of body tissue between one defibrillator paddle and an ELECTROCARDIOGRAPH ELECTRODE, since it is considered unlikely that both defibrillator ELECTRODES will be connected directly to the ELECTRODES of the ELECTROCARDIOGRAPH.

The value of the inductance L in the test circuits of Figures 201.102 and 201.103 is chosen to provide a faster than normal rise time in order to test adequately the incorporated protective means.

The switching period of 200 ms \pm 50 % is not critical, to the extent that "very briefly" would almost be an adequate replacement, but quoting a time gives an indication of scale.

As there are a number of possible LEAD combinations, any of which could be in use on a PATIENT at the moment of defibrillation and resulting in any of the LEADS being subjected to the defibrillation voltage, LEAD combinations are tested as shown in Table 201.103.

These combinations ensure that every ELECTRODE is tested and include the LEAD(S) most likely to be affected by the ELECTRODES connected to P1.

Future ELECTROCARDIOGRAPH performance standards may not require MANUFACTURERS to provide specific LEAD group selections, in which case the test house will have to modify Table 201.103 accordingly.

The requirement is for all CHANNELS to recover within 5 s. It is not acceptable that only one CHANNEL in a multi-channel ECG is readable within 5 s. There is no requirement that all LEADS be connected to the PATIENT.

Subclause 201.12.1.101.1 – Automated measurements on ECGS

Subclause 201.12.1.101.1 addresses the issue of ECG measurements and requirements on measurement accuracy. The requirements specified are based upon more than 10 years of

international research in the field of standardisation of quantitative electrocardiography. They are based upon performance testing results obtained from systems developed at universities and major companies still active and covering a major share of the world market.

The ECGS for the assessment of the accuracy of the ELECTROCARDIOGRAPH may be input in the ELECTROCARDIOGRAPH either in analogue or in digital form, or the measurement algorithm's performance may be assessed by testing it offline, using the same ECGS, provided that sufficient performance requirements are in place to ensure that the rest of the ELECTROCARDIOGRAPH is capable of acquiring, filtering, and outputting diagnostic quality ECGS.

Subclause 201.12.1.101.2 – Requirements for amplitude measurements

The CAL ECGS (Table GG.1) have accurately defined amplitudes for all waveforms (P, Q, R, S and T). But when these CAL ECGS are used by computer programs with different algorithms for delineation of the wave onsets and offsets, these programs may establish slightly different baseline values for amplitude measurements. The non-physiological nature of the CAL ECGS (steep slopes, sharp transitions, absence of spatial variation, etc.), may add another source of variability to the measurements generated by these computer programs, which have been primarily developed using real PATIENT ECGS. This would lead to deviations in the measured amplitudes relative to the reference voltages given in the CTS atlas. The acceptable limits (relative percentages and absolute micro volt limits) have been arrived at taking such possible deviations into consideration. For CAL ECGS of large deflections (CAL30000, CAL40000 and CAL50000) a higher limit in absolute μV is proposed for the same reason.

Subclause 201.12.1.101.3.1 – Requirements for absolute interval and wave duration measurements

When locating the fiducial points of the component waves (P, Q, R, S, T) of the CAL ECGS of the CTS atlas, computer algorithms may often move a couple of samples in or out of the actual transition points of the waveforms (see the rationale for section 201.12.1.101.2, Requirements for amplitude measurements). This would lead to deviations in the measured intervals and wave durations from the reference values given in the CTS atlas. The acceptable limits in Table 201.104 (means and standard deviations) have been arrived at taking such possible deviations into consideration.

Subclause 201.12.1.101.3.2 – Requirements for interval measurements on biological ECGS

The reference values for interval measurement accuracy are the median values of the fiducial points determined by 5 referee cardiologists (for 25 ECGS) and the median values of the 11 different computer programs (for the remaining ECGS) in the CSE measurement study [2]²⁾. Although these median values were used in the CSE study, there was a wide spread in the intervals measured by individual cardiologists and computer programs. This was particularly true for the P-wave onset and offset and T offset. Even for the QRS onset and offset, the variance was not negligible. The acceptable limits in Table 201.105 (means and standard deviations) have been arrived at taking the observed variance amongst the cardiologists and computer programs evaluated in the CSE study into consideration.

Subclause 201.12.4.101 – Indication of inoperable ELECTROCARDIOGRAPH

Indication of inoperability should be visible on the ECG REPORT, or the requirement may be fulfilled by the absence of a visible trace.

²⁾ Figures in square brackets refer to the Bibliography.

Subclause 201.12.4.103 – Input impedance

This test assures an input impedance of at least 2,5 MΩ. This is necessary in order to avoid excessive loss of signal amplitude due to high skin impedances.

Subclause 201.12.4.105.1 – COMMON MODE REJECTION

The 51 kΩ resistor in parallel with the 47 nF capacitor simulates effective imbalances in the ELECTRODE to represent skin impedance and the test circuit allows various types of compensating circuits to operate effectively.

Subclause 201.12.4.105.2 – Overload tolerance

ME EQUIPMENT should not be permanently damaged by accidentally applying a large input signal.

Subclause 201.12.4.105.3 – FILTERS (including line frequency interference FILTERS)

Filtering of an ECG signal can alter diagnostically important features such as the ST-segment and, thereby, adversely affect interpretation of the ECG REPORT. Thus the effect of filtering should be kept to levels where such a degradation of signal reproduction fidelity does not occur. Performance limits exist for the use of line frequency notch FILTERS. Ringing of these FILTERS should be kept below the minimal diagnostically significant voltage level. For all other FILTERS no actual limits are imposed. Nevertheless the USER should be made aware of the possibly deleterious effects of filtering by providing him with a warning that interpretation of the ECG may be affected whenever the FILTER might affect the signal representation (i.e. does not comply with the requirements of this standard).

Some modern ELECTROCARDIOGRAPHS have FILTERS permanently on, i.e., they are not switchable (e.g., the line FILTER may always be on). Notwithstanding, the test of 201.12.4.106.1 shall be done with all line FILTERS disabled, even if it requires a special version of software and hardware to do so. Tests for the requirements in 201.12.4.106.2 and 201.12.4.107.2 may be performed with non-switchable FILTERS on.

In order to check the COMMON MODE REJECTION of the ME EQUIPMENT's circuit, it is necessary to disable any line frequency notch FILTER. Otherwise, this test mostly checks the (differential mode) rejection of such a notch FILTER. It is desirable to achieve good COMMON MODE REJECTION at frequencies other than at the SUPPLY MAINS frequency.

Subclause 201.12.4.106.1 – NOISE level

The maximum 30 μV NOISE level is proposed because this is equivalent to 0,3 mm on an ECG REPORT at NORMAL GAIN and this value is close to the line thickness of the ECG.

Subclause 201.12.4.107.1 – Frequency response

Accurate reproduction of ECGs requires a sufficient bandwidth. Specifically, good high frequency response is needed to reproduce accurately Q- and R-waves and detail within waves, while good low frequency response is required for accurate reproduction of ST-segments (both level and slope) which influence certain diagnoses.

Traditionally, good high frequency response has been established by specifying the ELECTROCARDIOGRAPH's response to medium to high frequency sinusoidal signals, and good low frequency response by specifying a low cut-off frequency, e.g. 0,05 Hz for "diagnostic bandwidth". In recent years, specifying impulse response has become the preferred method for ensuring good low frequency response, and triangular waveforms have been added to sinusoidal signals in order to characterise high frequency response more completely. The low

frequency response was previously stated in terms of a low cut-off frequency of 0,05 Hz, which was sufficient to achieve accurate ST-segment reproduction even for a first-order FILTER with unspecified phase response. More sophisticated FILTERS are now commonly used which achieve equally accurate reproduction of ST-segment level, and adequate slope reproduction, even though the FILTERS have a higher cut-off frequency and thus faster baseline recovery. Hence, low frequency response requirements are now stated in terms of impulse response requirements. The requirements specified in 201.12.4.107.1.1.2 are sufficient to ensure adequate ST-segment reproduction and are also equivalent to the calibration ECG requirements of 201.12.4.107.1.2, as they should be. The triangular wave shape used in the test of the high frequency response more closely approximates QRS-complexes, as opposed to sinusoids. The 20 ms base width of the test waveform corresponds to a worst-case R wave duration for infants. The rate of change is below 320 mV/s. The 12 % allowable reduction in peak amplitude of the applied triangular signal is based on theoretical calculations and bench tests to obtain comparability of performance with that of linear systems having 150 Hz bandwidth. Hence, 201.12.4.107.1 on frequency response begins by specifying the response to sinusoidal signals, triangular signals and impulses.

However, some digital ELECTROCARDIOGRAPHS that include signal quality checks and pre-processing do not accept pure sinusoidal input signals. Since the purpose of specifying frequency response is to ensure accurate reproduction of ECGs, the most direct test is to measure the ELECTROCARDIOGRAPH response to precisely known test ECGs which are compiled in the “CTS Test Atlas”.

Consequently, MANUFACTURERS have a choice for demonstrating adequate bandwidth and frequency response: either traditional methods, with specifications given in 201.12.4.107.1.1 or calibration ECG methods, with specifications given in 201.12.4.107.1.2. Of course, completely different methods cannot be expected to always yield identical results. It is possible that an ELECTROCARDIOGRAPH may barely meet 201.12.4.107.1.1 specifications while barely failing 201.12.4.107.1.2 or vice versa. This should be a rare instance. The specifications of either 201.12.4.107.1.1 or 201.12.4.107.1.2 are sufficient to ensure sufficiently accurate reproduction of ECGs.

Subclause 202.6.2.1.10 – Compliance criteria

To restrict the amount of testing, only the most critical part of an ECG, the amplitudes, especially the ones of an ST segment deviation, are tested. Similar tests apply for subclauses 202.6.2.4.1 and 202.6.2.6.1.

Subclause 202.6.2.101 – Electrosurgery interference

There is no ideal test method to generate electrosurgical interference in a test laboratory but the one given in Figures 202.103 and 202.104 has been shown by experience to reproducibly give results similar to those seen in surgical practice. The test should be done in the normal working range of the HF SURGICAL EQUIPMENT (load approximately 500 Ω). Sparking (short time event), but not arcing (long time event) should be avoided as it may cause inconsistent results.

Disturbances caused by HF SURGICAL EQUIPMENT are considered NORMAL USE and consequently should not result in HAZARDS to the PATIENT. Therefore, after an appropriate recovery time the ME EQUIPMENT should resume normal operation without loss of stored data. The instantaneous heart rate or the displayed ECG waveform do not fall under stored data.

The most critical test is the application of a common-mode HF voltage as shown in Figure 202.103. Capacitive coupling of HF to functional earth may interfere with central processing units preventing that the ME EQUIPMENT fails to recover the specified time or does not recover at all. For this reason it is not necessary to perform this test with a differential-mode HF voltage.

AA.3 Guidelines to input ECG data to ELECTROCARDIOGRAPHS

NOTE These guidelines are applicable to 201.12.1.101 and parts of subclauses 201.12.4.102 through 201.12.4.109.

The following guidelines can be used to input the digital ECGs to the ELECTROCARDIOGRAPH for testing the performance functions requiring a specified ECG input. Examples of such digital ECGs include CTS calibration and analytical ECGs, biological ECGs, ECGs of the Diagnostic ECG Database and ECGs of the Rhythm ECG Database.

Digital waveform data can be digital-to-analogue (D/A) converted and applied as analogue signals to the acquisition module (front-end) of the ELECTROCARDIOGRAPH. As standard procedures for D/A conversion are beyond the scope of this standard, individuals testing ELECTROCARDIOGRAPHS for compliance to this standard can devise suitable methods with the following suggested features.

- Store 10 s ECGs in a circular buffer and play them through the D/A converter as continuous signals.
- If partial P-QRS-T waves are present at the beginning and/or end of the record, exclude them while inputting into the ELECTROCARDIOGRAPH via the circular buffer.
- If the first and the last samples of ECG differ significantly in their voltage levels, apply a linear interpolation method to bring them to the same level. This will eliminate discontinuity at the wrap around in the circular buffer and the resulting potential errors in the analysis.

To calculate the body surface potentials from the stored ECG waveforms, connect the right arm and the right foot ELECTRODE of the ELECTROCARDIOGRAPH to ground. Feed LEAD I into the left arm ELECTRODE (since $I = L (LA) - R (RA)$ and $R (RA) = 0$, $L (LA) = I$), LEAD II into the left foot ELECTRODE; in the $C_i (V_i)$ ELECTRODES feed $C_i (V_i) = V(oltage)_i + (I + II)/3$ (since $V(oltage)_i = C_i (V_i) - (L (LA) + R (RA) + F (LL))/3$, $C_i (V_i) = V(oltage)_i + (L (LA) + R (RA) + F (LL))/3$, and, as $L (LA) = I$ and $F (LL) = II$ and $R (RA) = 0$, $C_i (V_i) = V(oltage)_i + (I + II)/3$). It may be convenient to adjust the D/A converter to put out a voltage 100 to 1 000 times higher than the original value (e.g. 1 V instead of 1 mV), and to reduce the analogue signal accordingly. This results in a cleaner input to the ELECTROCARDIOGRAPH.

Annex BB (informative)

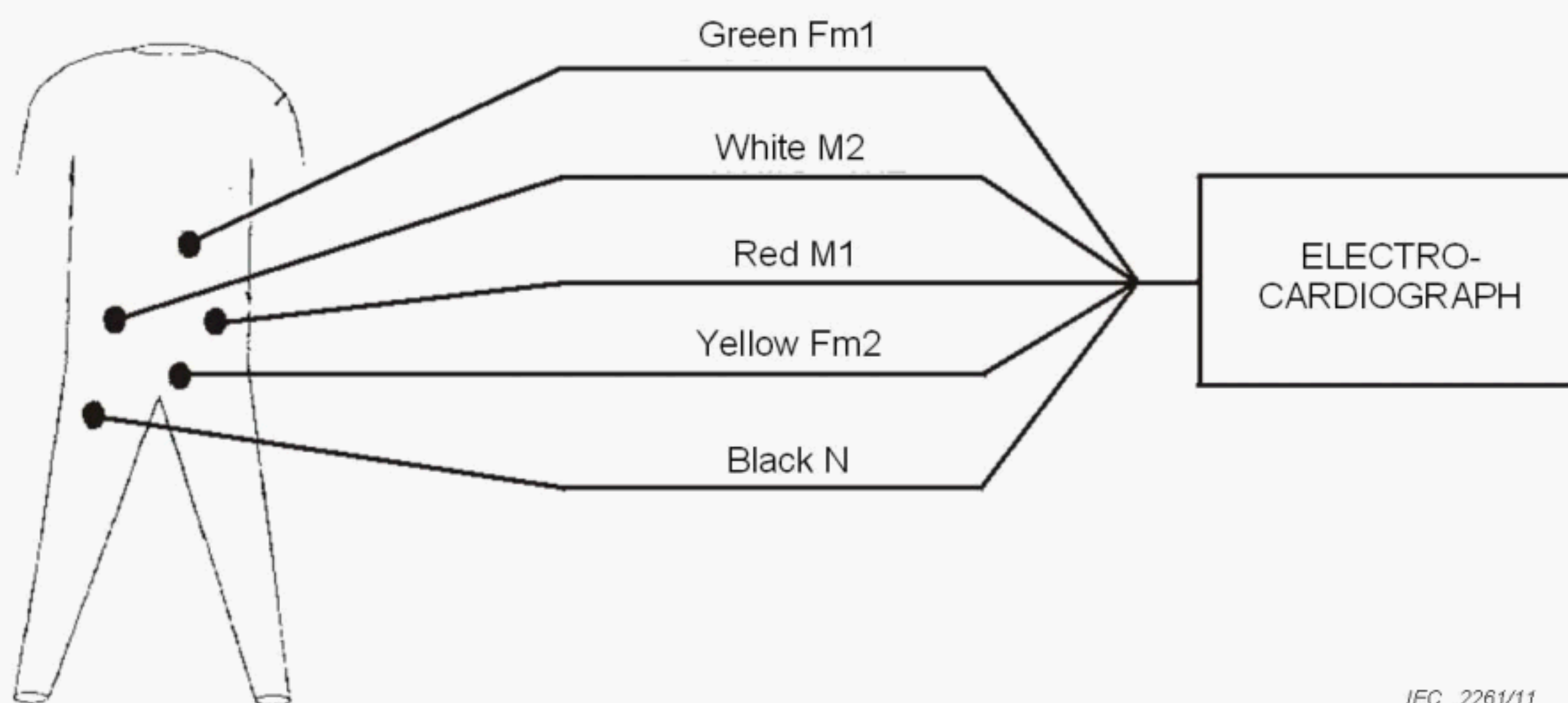
ELECTRODES, their positions, identifications and colour codes

**Table BB.1 – ELECTRODES, their positions, identifications and colour codes
(other than described in 201.7.4.101, Table 201.106)**

System	ELECTRODE identifier	Colour code	Position on body surface
Chest according to Wilson	C7	White/orange	Left posterior axillary line at the horizontal level of C4
	C8	White/blue	Left midscapular line at the horizontal level of C4
	C3r	White/pink	Fifth rib between C1 and C4r
	C4r	White/grey	Fifth intercostal space on right midclavicular line
Chest according to Nehb	Nst		Sternal attachment of the second rib right
	Nap		Apex beat
	Nax		Left posterior axillary line at the level of the apex beat
These abbreviations are not intended to represent internationally agreed ELECTRODE placements. Other ELECTRODE positions may be used.			

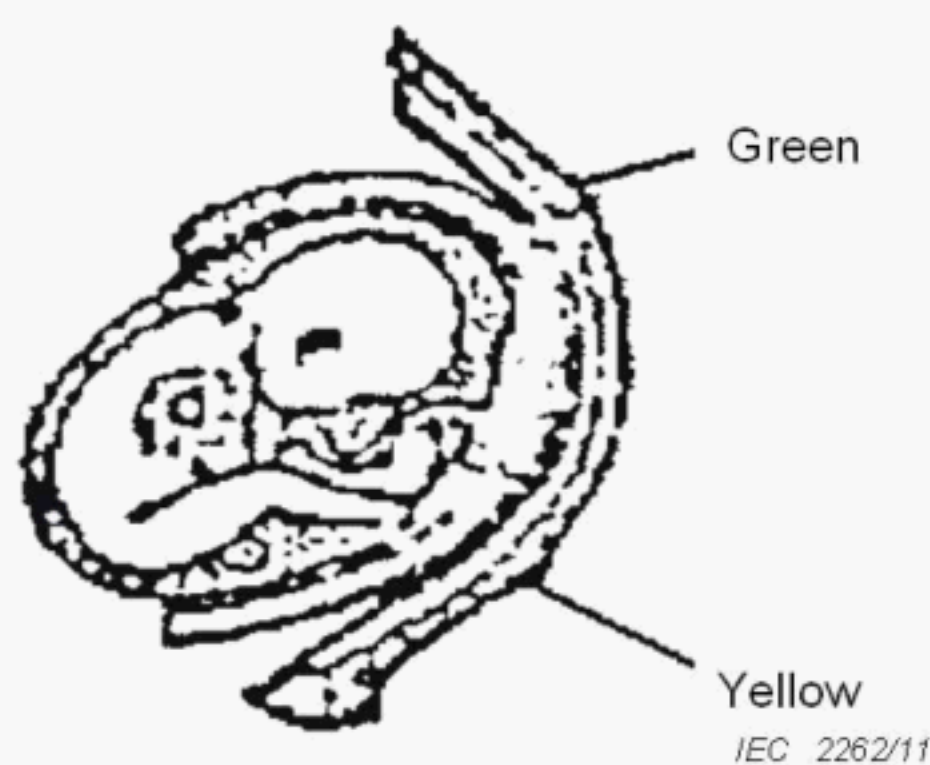
**Table BB.2 – Other ELECTRODE-positions, identifications and colour codes
not covered by this particular standard**

System	ELECTRODE identifier	Colour code	Position on body surface
Other LEAD ELECTRODE POSITIONS	B		Back
	Oe		Oesophageal
	G		Gastric
	Fr		Frontal is reference (for exercise ECG instead of CT)
	Ec		Epicardial
	Ic		Intracardiac
	Fm1	Green	Fetal ELECTRODE
	Fm2	Yellow	Fetal ELECTRODE indirect fetal ELECTRODES
	M1	Red	Maternal (see Figure BB.1)
	M2	White	Maternal
	N	Black	Neutral
	Fe1	Red	Fetal scalp ELECTRODE direct fetal ELECTRODES
	Fe2	Yellow	Maternal vagina (see Figure BB.2)
	N	Black	Neutral
When using more than one intracardiac ELECTRODE, these should be identified by Ic1, Ic2, Ic3, etc. and the method of connection, e.g. monopolar or bipolar, should be described in the accompanying documents. These abbreviations are not intended to represent internationally agreed ELECTRODE placements. Other ELECTRODE positions may be used.			



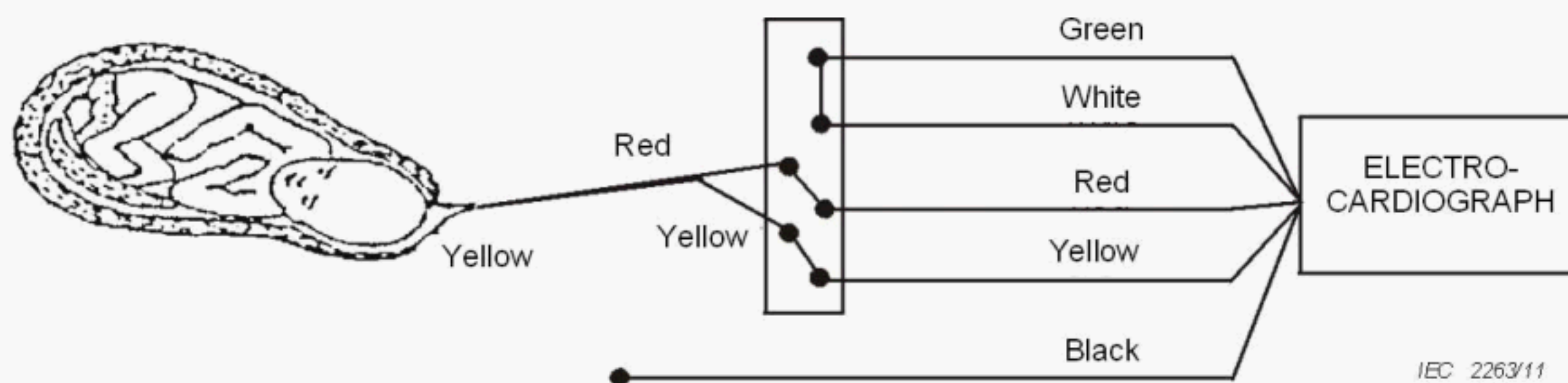
IEC 2261/11

Figure BB.1a – LEADS and colours for fetal ECG
(see Table BB.2)



IEC 2262/11

Figure BB.1b – Positions of the ELECTRODES on the fetus for fetal ECG
(see Table BB.2)



IEC 2263/11

Figure BB.2 – LEAD positions and colours for fetal scalp ECG
(see Table BB.2)

Annex CC (informative)

LEADS, their identification and colour codes (other than those specified in 201.12.4.102)

CC.1 Unipolar chest LEADS according to Wilson

From one of the ELECTRODES on the chest to the CENTRAL TERMINAL ACCORDING TO WILSON (CT)

$$V7 = C7 - (L + R + F) / 3 \quad (V7 - (LA + RA + LL))$$

$$V8 = C8 - (L + R + F) / 3 \quad (V8 - (LA + RA + LL))$$

$$V3r = C3r - (L + R + F) / 3 \quad (V3r - (LA + RA + LL))$$

$$V4r = C4r - (L + R + F) / 3 \quad (V4r - (LA + RA + LL))$$

CC.2 Bipolar chest LEADS

From one of the ELECTRODES on the chest to a common reference ELECTRODE (e.g. Fr: Frontalis). E.g.:

$$C1Fr = C1 (V1) - Fr$$

$$C2Fr = C2 (V2) - Fr$$

$$C3Fr = C3 (V3) - Fr$$

$$C4Fr = C4 (V4) - Fr$$

$$C5Fr = C5 (V5) - Fr$$

$$C6Fr = C6 (V6) - Fr$$

$$C7Fr = C7 (V7) - Fr$$

$$C8Fr = C8 (V8) - Fr$$

$$C3rFr = C3r (V3r) - Fr$$

$$C4rFr = C4r (V4r) - Fr$$

CC.3 Unipolar limb LEADS

From one of the ELECTRODES on the limbs to the central terminal according to WILSON (CT)

$$VR = R - (L+R+F)/3 \quad (RA - (LA+RA+LL)/3)$$

$$VL = L - (L+R+F)/3 \quad (LA - (LA+RA+LL)/3)$$

$$VF = F - (L+R+F)/3 \quad (LL - (LA+RA+LL)/3)$$

CC.4 Chest LEADS Nehb

$$D \text{ (dorsal)} \quad D = Nax - Nst$$

$$A \text{ (anterior)} \quad A = Nap - Nst$$

$$J \text{ (inferior)} \quad J = Nap - Nax$$

Annex DD (informative)

Polarity of PATIENT LEADS (other than those specified in 201.12.4.102)

The polarity of PATIENT LEADS other than those specified in subclause 201.12.4.102 should be as indicated in Table DD.1.

Table DD.1 – ELECTRODE polarities

LEAD	Positive ELECTRODE	Negative ELECTRODE
C..Fr	C.. (V..)	Fr
VR	R (RA)	R (RA), L (LA), F (LL)
VL	L (LA)	R (RA), L (LA), F (LL)
VF	F (LL)	C (V), L (LA), F (LL)
D	Nax	Nst
A	Nap	Nst
J	Nap	Nax

Annex EE (informative)

Additional marking of ELECTRODES

EE.1 Combined use ELECTRODES

If a separate cable is not provided, then LEAD ELECTRODES may also be marked for a second LEAD ELECTRODE position, e.g. for Frank LEADS:

C1 (V1) and I C4 (V4) and A
C2 (V2) and E C5 (V5) and M
C3 (V3) and C C6 (V6) and H

In the case of a colour coded PATIENT CABLE, the colour sequence from the Wilson chest ELECTRODES C1 (V1) to C6 (V6) is the same for the Frank chest ELECTRODES from ELECTRODE I at the right midaxillary line to ELECTRODE M at the back midline.

EE.2 Combined standard and Frank ELECTRODES

Where a combined PATIENT CABLE with 14 wires is used for Standard LEAD and Frank LEAD ELECTRODES the identification and colour code in Table EE.1 is recommended:

**Table EE.1 – Recommended identification and colour code
for a 14-wire PATIENT CABLE**

<u>Code 1</u>		<u>Code 2</u>	
R	Red	RA	White
L	Yellow	LA	Black
F	Green	LL	Red
C1	White/red	V1	Brown/red
C2	White/yellow	V2	Brown/yellow
C3	White/green	V3	Brown/green
C4/C	White/brown	V4/C	Brown/blue
C5	White/black	V5	Brown/orange
C6/A	White/violet	V6/A	Brown/violet
I	Light blue/red	I	Orange/red
E	Light blue/yellow	E	Orange/yellow
M	Light blue/black	M	Orange/black
H	Light blue/violet	H	Orange/violet
N	Black	RL	Green

Annex FF (informative)

Definitions and rules for the measurement of ELECTROCARDIOGRAMS

FF.1 The ELECTROCARDIOGRAM

The ELECTROCARDIOGRAM (ECG) is the graphical display of a series of electrical phenomena resulting from atrial and ventricular depolarization and repolarisation within the heart.

Since Einthoven, the terms P-wave (P-complex), QRS-complex, ST-T- have been used to describe these phenomena (see Figure FF.1).

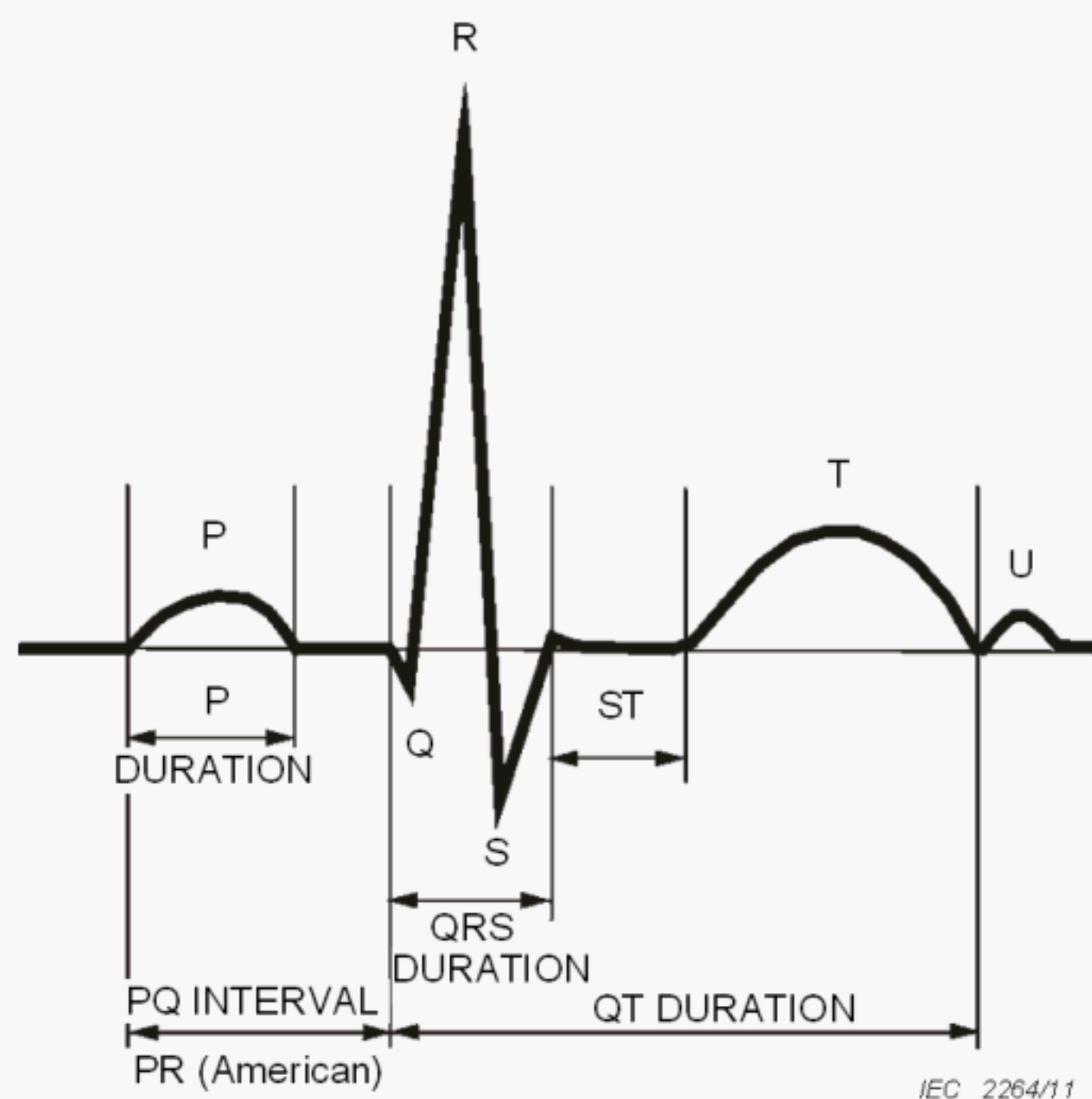


Figure FF.1 – Normal ELECTROCARDIOGRAM

FF.2 Determination of global intervals

The global duration of P, QRS and T are physiologically defined by the earliest onset in one LEAD and the latest offset in any other LEAD (wave onset and offset do not necessarily appear at the same time in all LEADS because the activation wavefronts propagate differently). Figure FF.2 is an example, where P-onset is determined by LEAD II, P-offset is determined by LEAD I, QRS-onset is determined by LEAD V1 and LEAD V3, QRS-offset is determined by LEAD V5 and T-offset is determined by LEAD V2 and V3.

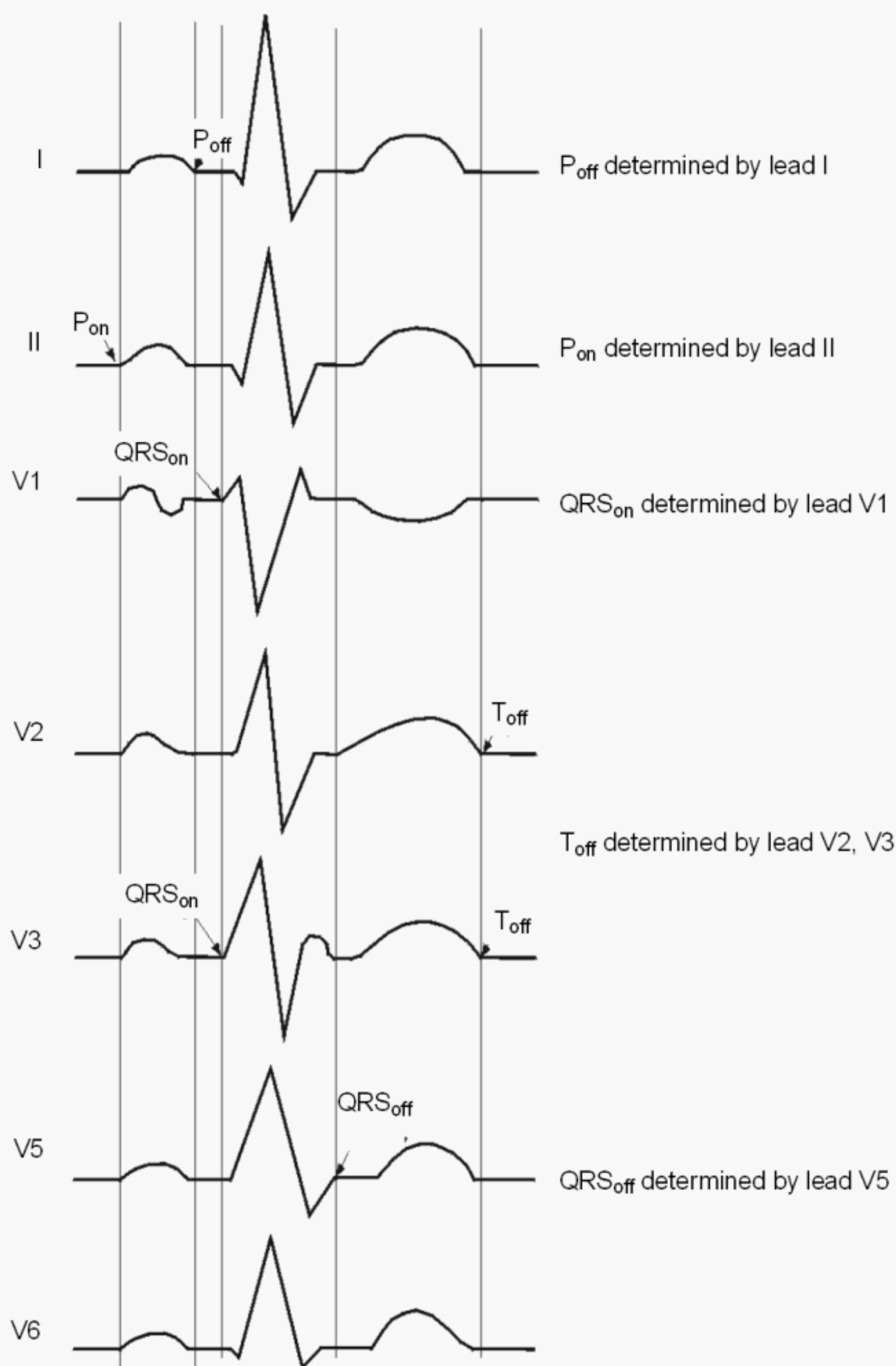


Figure FF.2 – Determination of global intervals (example)

FF.3 Waveform durations, isoelectric segments

Because of the physiological definitions for the global onsets and offsets, isoelectric segments may be observed within single LEADS at the beginning as well as at the end of the QRS-complex. In the publication "Recommendations for Measurement Standards in Quantitative Electrocardiography", the CSE working group proposed that the isoelectric segments at onset and offset of the QRS complex shall be counted separately, if they are longer than 6 ms, instead of including the duration of these segments in the duration of the adjacent wave. Figure FF.3 gives an example.

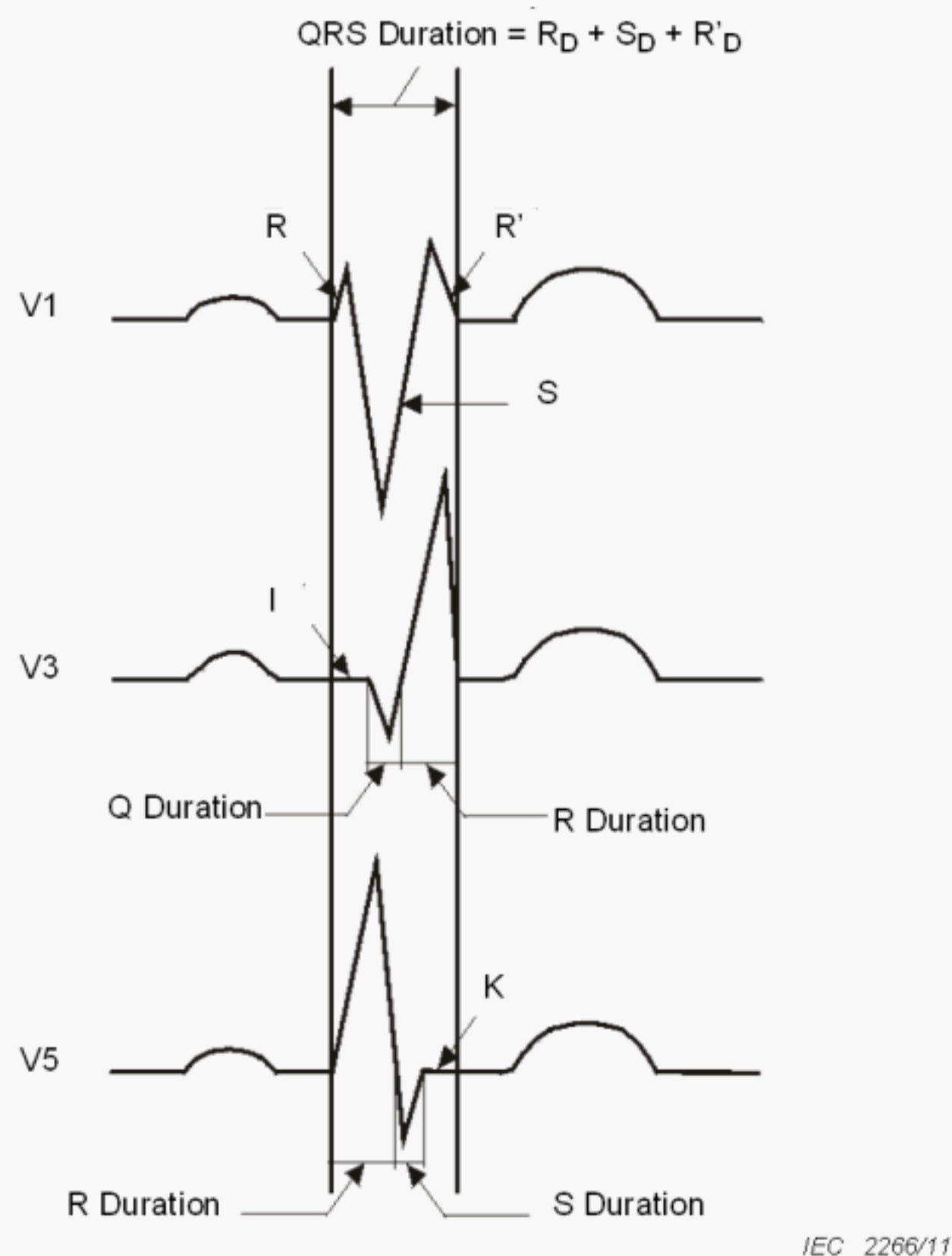


Figure FF.3 – Waveform durations, isoelectric segments

FF.4 Baseline (amplitude measurement references)

The baseline is a reference potential determined, for example, at onset of P-wave or at onset of QRS-complex. For computer measurement this value is usually the result of a search-and/or an arithmetic computation. The baseline is the reference for the determination of amplitudes of ECG waveforms.

For atrial activity, the baseline might be determined as an arithmetic mean of samples covering a complete period (e.g., 20 ms for 50 Hz or 16 ms for 60 Hz) immediately preceding the P-wave's onset. Other methods for determining this baseline at the P-wave-onset are feasible.

The AHA and CSE recommendations suggest that the baseline levels at P-onset, or at QRS-onset should be used as the reference amplitude for the whole P-wave and for the whole QRS-interval respectively. Within the CSE publication a “baseline correction” is assumed.

Sometimes this is best achieved by linear interpolation between P-onset and P-offset or QRS-onset and T-offset. To date no clear and practically useful rule is available.

NOTE It is desirable that a standardised procedure be applied. Amplitude measurements are usually point estimates. The confidence interval for the value of an amplitude depends upon the confidence interval of the baseline (reference value) as well as upon the value selected at the point of amplitude measurement. By means of “stabilisation” of the baseline the confidence interval for the amplitude measurement can be markedly reduced.

FF.5 Definition of waveforms, measurement of minimum waves

In contrast to a simple deflection (elevation or depression) with reference to the base level, a wave has two opposite slopes and at least one turning point, convex for a positive wave, or concave for a negative wave.

Recognition of small waveform segments obviously depends on how much noise is present on the signal. The CSE study showed that experts, even when using highly enlarged recordings, cannot reliably recognise waveforms with durations < 6 ms or amplitudes $< 20 \mu\text{V}$. Investigations on sampling rate and measurement accuracy show unacceptably large errors in determining peak-amplitudes for durations $< \approx$ (sampling interval $\times 6$). Unreliable detection of small waveforms within the QRS complex that change the QRS labelling (a Q-wave may become an S-wave if a small positive wave precedes it) cause problems within databases, serial comparisons and epidemiological studies.

In light of extensive testing, the recommended rule for acceptance of minimum waves is:".

Replace a) – c) and the note with:

- a) the potential wave clearly shows two opposite slopes separated by a turning point;
- b) the peak amplitude of the potential wave is at least $30 \mu\text{V}$ from the reference level for at least 6 ms (see Figures FF.5 and FF.6);
- c) the resulting minimum acceptance criteria for waves is observable durations of ≈ 12 ms and amplitudes $\geq 30 \mu\text{V}$.

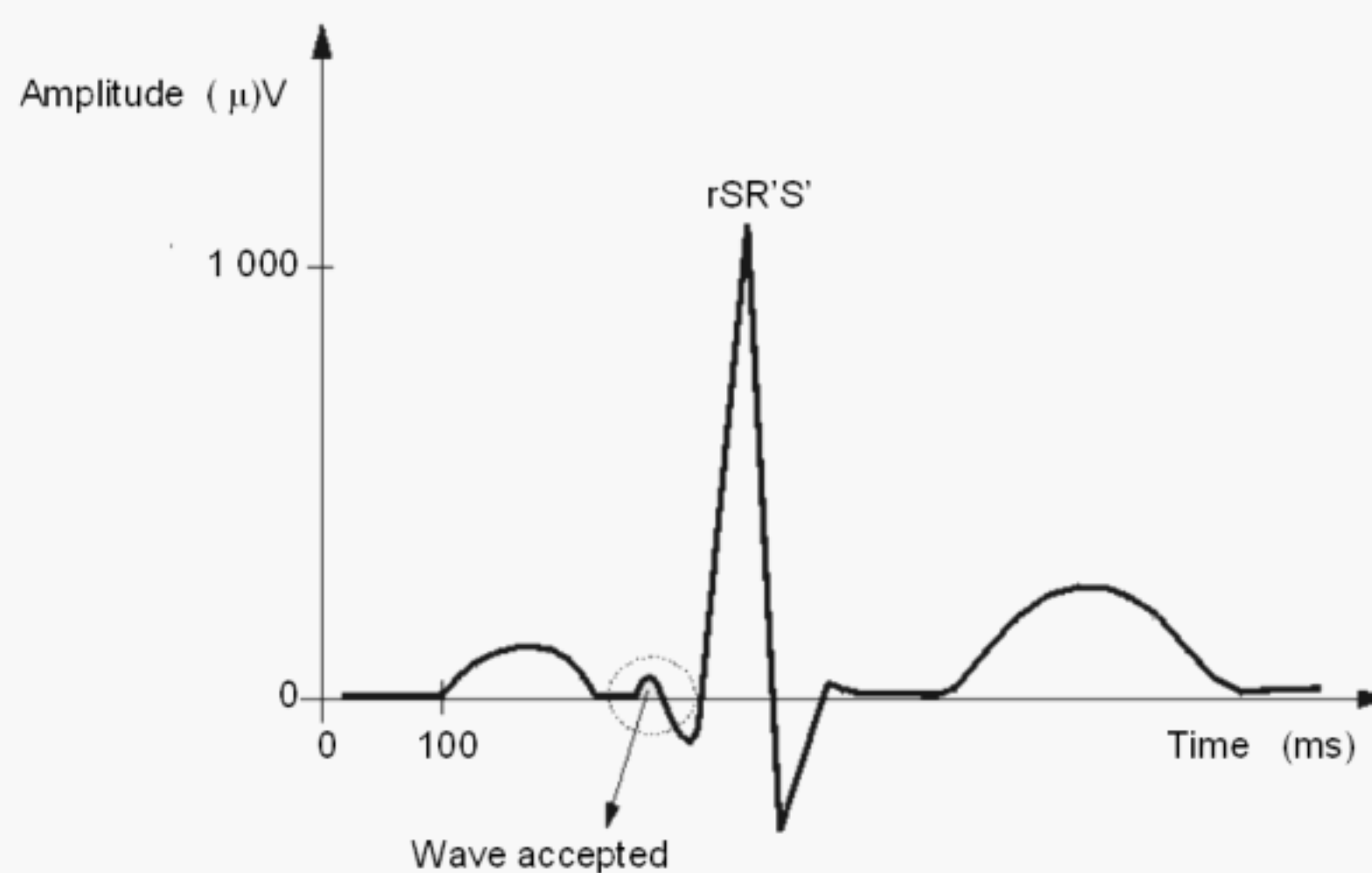
NOTE Future consideration should be given to whether this minimum acceptance criterion is principally based upon a standardised noise measurement procedure and a standardised significance test.

Between the global onset and offset of the QRS-complex, signal parts with a duration of more than 6 ms and amplitudes not exceeding $20 \mu\text{V}$ for at least three samples should be defined as isoelectric segments – I before the global QRS-onset and K after the global QRS-offset.

If those signal parts occur between accepted Q-, R- and S-waves *within* the QRS-complex, the duration of the adjacent (opposite) waveforms should be determined by its zero level (or reference level) crossings.

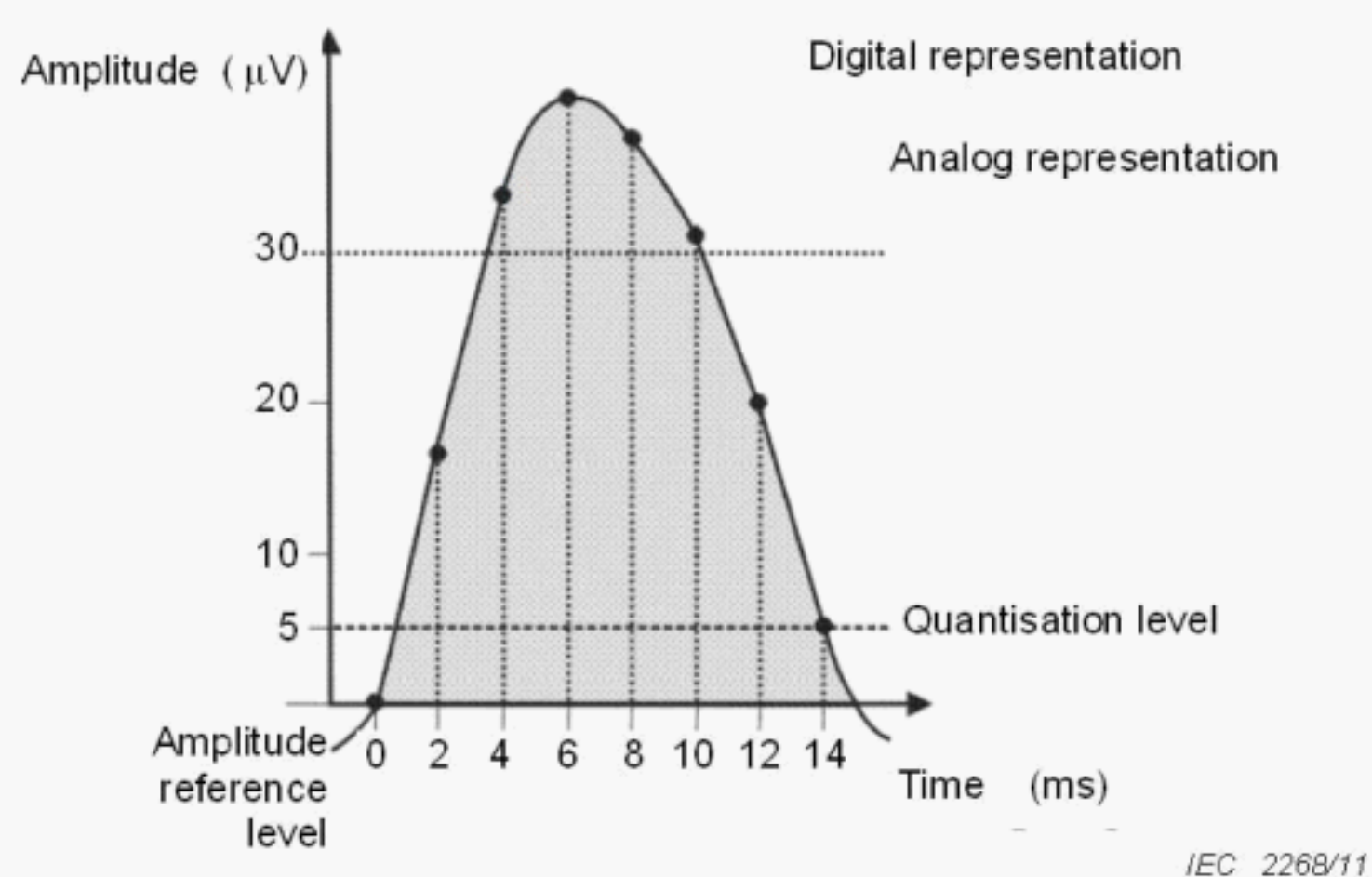
FF.6 Acceptance of minimum waves

The labelling of the QRS complex depends by definition (since Einthoven) on the first detected wave. A tiny positive wave at QRS beginning is called r or R and may mask a true, following Q wave. Therefore the acceptance criteria of initial waveforms should be clearly defined and standardised.



IEC 2267/11

Figure FF.4 – QRS complex with small R-wave(s)
(see Figure FF.5, FF.6)



To be accepted because duration above 30 μV ≥ 6 ms.

Figure FF.5 – Detail of small accepted R-wave

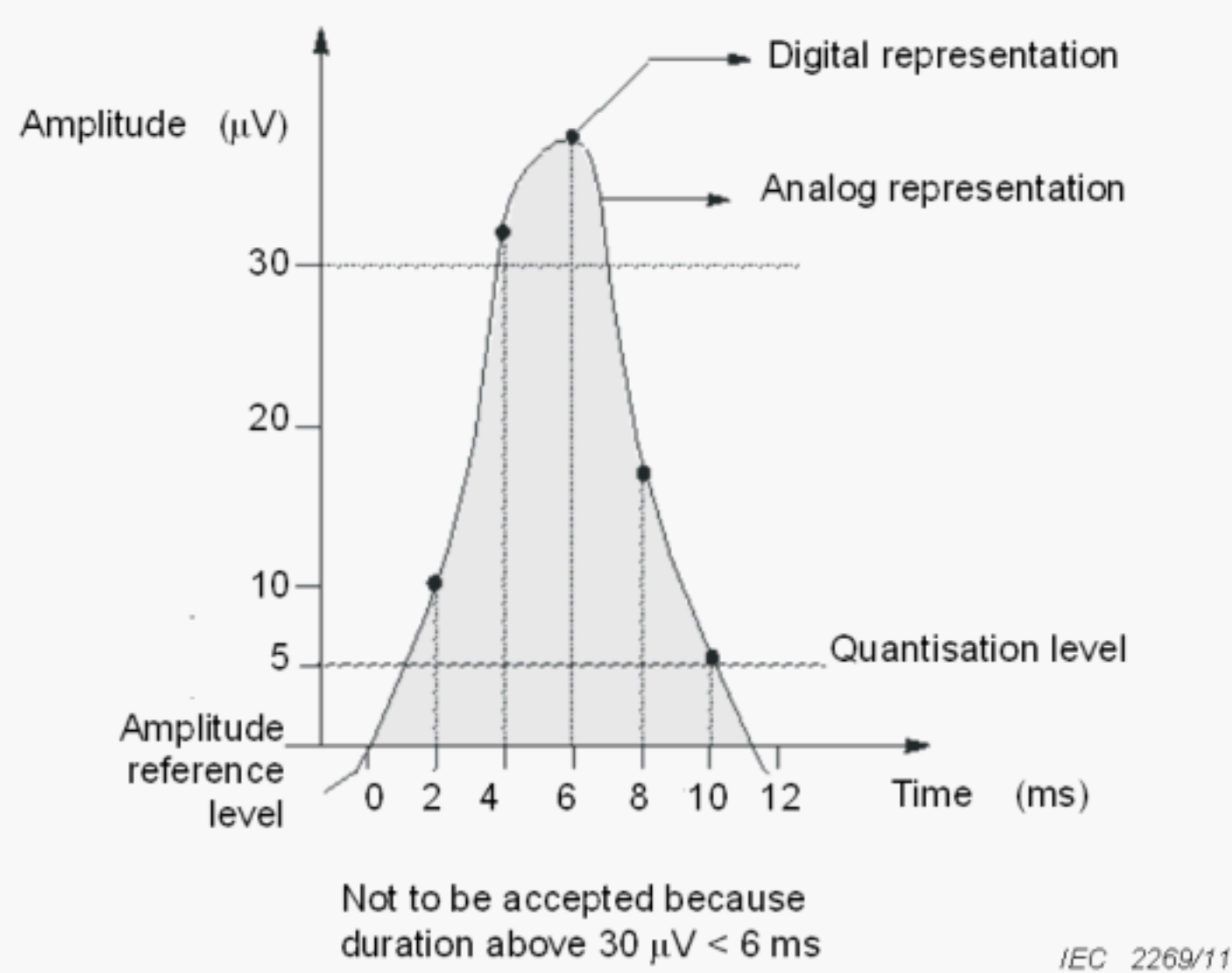


Figure FF.6 – Detail of small rejected R-wave

Annex GG (informative)

Calibration and test data sets

The following table lists the recommended CALIBRATION ECGS and analytical ECGS for testing. These ECGS are available in electronic form, at 1 000 samples/s and 500 samples/s and an amplitude resolution of 1 $\mu\text{V}/\text{LSB}$. These ECGS are from the Common Standards for Quantitative Electrocardiography (CSE) Databases. They are available on CD-ROM from INSERM Unit 121, Hopital Cardiologique, 59 Boulevard Pinel, BP Lyon-Montchat, 69394 Lyon Cedex 3 France. The reference results from these ECGS are delivered upon ordering the CD-ROM. The denomination is as follows:

- a) formulated for DOS-compatibility (for management on PC);
- b) digits 1 and 2 characterise the peak-QRS voltage (mV);
- c) digit 3 characterises the QRS-form (0 = RS, 1 = R, 2 = QS, 5 = small RS (approx. paediatric ECG));
- d) digit 4 characterises ST (0 = 0 μV , 1 = –200 μV , 6 = +200 μV);
- e) digit 5 characterises the heart rate (0 = 60/min, 1 = 40/min, 2 = 120/min, 3 = 150/min).

GG.1 CALIBRATION and analytical ECGS

Table GG.1 – CALIBRATION and analytical ECGS

QRS Type/Voltage	HR	Denomination	Applicable to subclause
CALIBRATION ECGS			
$\pm 0,5$ mV ST = 0	60	CAL05000	201.12.1.101.2, 201.12.1.101.3.1, 201.12.4.107.2
$\pm 1,0$ mV ST = 0	60	CAL10000	201.12.1.101.2, 201.12.1.101.3.1, 201.12.4.102.3.1, 201.12.4.102.3.2
$\pm 1,5$ mV ST = 0	60	CAL15000	201.12.1.101.2, 201.12.1.101.3.1, 201.12.4.102.3.2
$\pm 2,0$ mV ST = 0	60	CAL20000	201.12.1.101.2, 201.12.1.101.3.1, 201.12.4.102.3.1, 201.12.4.102.3.2, 201.12.4.107.1.2, 201.12.4.107.2
$\pm 2,0$ mV ST = 0	120	CAL20002	201.12.1.101.2, 201.12.1.101.3.1
+2,0 mV ST = 0	60	CAL20100	201.12.1.101.2, 201.12.1.101.3.1, 201.12.4.107.1.2
+2,0 mV ST = –200	60	CAL20110	201.12.1.101.2, 201.12.1.101.3.1, 201.12.4.107.1.2, 202.6.2.1.10, 202.6.2.4.1, 202.6.2.6.1
+2,0 mV ST = +200	60	CAL20160	201.12.1.101.2, 201.12.1.101.3.1, 201.12.4.107.1.2
–2,0 mV ST = 0	60	CAL20200	201.12.1.101.2, 201.12.1.101.3.1, 201.12.4.107.1.2
–2,0 mV ST = 200	60	CAL20210	201.12.1.101.2, 201.12.1.101.3.1
–2,0 mV ST = +200	60	CAL20260	201.12.1.101.2, 201.12.1.101.3.1
$\pm 2,0$ mV ST = 0	60	CAL20500	201.12.1.101.2, 201.12.1.101.3.1, 201.12.4.107.1.2
$\pm 3,0$ mV ST = 0	60	CAL30000	201.12.1.101.2, 201.12.1.101.3.1, 201.12.4.102.3.1, 201.12.4.102.3.2, 201.12.4.103
$\pm 5,0$ mV ST = 0	60	CAL50000	
Analytical ECGS			
QRS normal	40	ANE20001	201.12.1.101.2, 201.12.1.101.3.1
QRS normal	60	ANE20000	201.12.1.101.2, 201.12.1.101.3.1, 201.12.4.105.3
QRS normal	120	ANE20002	201.12.1.101.2, 201.12.1.101.3.1

These ECGS are shown in the CTS ECG Test Atlas.

GG.2 Biological ECGs

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

ECG denomination from the CSE measurement database MA1_ or MO1_ series				
001	026	047	074	098
002	027	048	075	099
003	028	049	076	101
004	029	051	077	102
005	030	053	078	103
007	031	055	079	104
008	032	058	080	105
009	033	059	081	106
011	034	060	082	107
012	035	061	083	108
013	036	062	084	110
014	037	063	085	112
015	038	064	086	113
016	039	065	087	114
017	040	066	088	115
019	041	068	090	116
021	042	069	091	118
022	043	071	095	123
024	044	072	096	124
025	046	073	097	125

Annex HH (informative)

CTS test atlas

HH.1 Introduction

Systems with integrated digital signal processing do not behave as linear systems, so sinusoidal and step function test signals may not be appropriate for verifying the performance of such systems. This led to development of a new set of test signals. These signals have an ECG-like shape and can be used for testing both older analogue ELECTROCARDIOGRAPHS, which only record ECGs, and newer ELECTROCARDIOGRAPHS with integrated signal processing, which provide measurements and interpretative statements.

The CTS reference signals (mainly the CAL-ECGs) are stored as single cycle artificial ECG waveforms within the CTS database. These signals may then be used by means of specific programs to generate continuous signals of any desired duration. After digital to analogue conversion these signals have to be scaled down to the typical ECG. The CTS reference signals may also be used to produce artificial ECG REPORTS which can be used for testing stand-alone analysis programs.

The authors of this atlas consider these test signals to be a way to measure the updated IEC performance requirements for ELECTROCARDIOGRAPHS. The atlas' test signals will ease and improve system testing for MANUFACTURERS. They can often be used instead of the inadequate sinusoidal and step function signals which only indirectly provide information on accurate reproduction and measurement of ECG signals.

HH.2 The test database

HH.2.1 Rationale

Some ELECTROCARDIOGRAPHS currently on the market either only print ELECTROCARDIOGRAMS (ECG REPORTS) or display them on video screen; others (in ELECTROCARDIOGRAPHS with integrated signal processing) provide measurements and interpretative statements. The separation between hardware and software is disappearing since digital electronic circuits are replacing analogue signal processing. Integration of signal processing into the front-end part of modern ELECTROCARDIOGRAPHS often introduces non-linear characteristics. This makes it impossible to assess the system performance on the basis of linear systems theory. Applying conventional test signals (e.g., periodic sine waves and step functions) may not suffice to verify performance specifications. Specific FILTER algorithms for line frequency interference reduction, baseline wander suppression and spike removal may prevent reproduction of these conventional test signals. Therefore conventional testing of an ELECTROCARDIOGRAPH'S hardware according to test specifications (test circuits, test signals, test procedures) is sometimes impossible.

Moreover a number of ELECTROCARDIOGRAPHS provide measurements and interpretative statements for ELECTROCARDIOGRAMS. So far neither specifications nor requirements exist for their performance in terms of measurement and diagnostic accuracy.

During the European CTS-ECG project it was realized that new test methods need to be developed. Part of this was the design of test signals which can be fed into both older analogue and newer digital ELECTROCARDIOGRAPHS. It was a major goal to create signals that can be used for signal reproduction verification on paper-strip as well as for computer programs which have been designed for measurement and interpretation of ELECTROCARDIOGRAMS.

As a result a set of ECG-like signals with well defined amplitude-time characteristics were created. The signals are generated in digital form and can be used to analyse both

- the hardware characteristics of analogue systems in terms of amplifier linearity, gain factors, weighting factors for LEAD networks, low and high frequency response, and signal reproduction on printed reports;
- the software performance, for example in terms of waveform detection, recognition of fiducial points, measurement of ECG parameters, etc.

The set of almost 20 waveforms can be used to generate test signals of any length. These signals are part of the CTS-ECG test database and have already proven their usefulness in a series of pilot tests.

On the following pages the design characteristics of these test signals are described in more detail and the waveforms and their measurements are printed out.

HH.2.2 Set-up of the test database

The test signals have the following characteristics:

- All signals are defined by mathematical functions. The amplitudes are defined for each sample, intervals between characteristic waveforms as well as the durations of the waveforms are exactly specified.
- All signals have an ECG-like shape. They can be applied to systems which simply print ECG data as well as to systems which apply specific ECG signal recognition and NOISE rejection algorithms (for example line frequency suppression, baseline wander removal, and spike detection).
- The signals allow testing of major hardware aspects, for example calibration, amplifier linearity, LEAD weighting networks, gain factors, and signal reproduction as conventionally expressed in terms of high and low frequency response.
- The signals also make software testing possible because they can be processed like ECGs and accuracy of amplitude and interval measurements can be verified directly by means of the output lists (if provided).
- According to the structure of an ECG REPORT each of the test signals consists of one cycle. This cycle can be repeated indefinitely for testing. The repetition rate can be changed for various tests.
- All signals are available in digital form (source see Annex GG) with sample rates of 1 000 samples/s and 500 samples/s and with 1 μ V amplitude resolution. The signals include the LEADS I, II, V1, V2, V3, V4, V5, and V6.

Two kinds of test signals have been developed so far:

- “calibration ECGS”,
- “analytical ECGS”.

The “calibration ECGS” are mainly used to test an ELECTROCARDIOGRAPH’S hardware characteristics. Therefore the signal form is the same for all channels (I, II, V1, ..., V6).

The “analytical ECGS” have been developed to test ECG analysis algorithms more realistically. They have a signal form which is close to a normal ECG with different wave shapes in all LEADS.

HH.2.3 Calibration ECGS

The calibration ECGS are designed to test system performance over a ± 5 mV amplitude range. Therefore, peak amplitudes in steps of 500 μ V or 1 000 μ V starting at ± 500 μ V are provided.

Besides amplitude reproduction the capability of the systems to reproduce a signal's high frequency and low frequency components is relevant. Therefore, some calibration ECGs have very short "QRS" complexes (36 ms) and some include elevated or depressed "ST" segments.

Figure HH.3 shows the fundamental shape of a calibration ECG. These signals include waveforms, which with regard to amplitudes and durations are similar to P, Q, R, S or T waves, so these signals are described using ECG terminology.

NOTE The interval between P wave and QRS onset is the PR interval in English, but is the PQ interval in German.

Specific characteristics of the calibration ECGs are:

- *Identical LEADS.* The eight LEADS I, II, V1, V2, V3, V4, V5, and V6 are identical for each calibration ECG. This allows simultaneous testing of each channel.
- *Flat maximum amplitudes.* To make sure that the maximum amplitudes of the relatively short QRS deflections are picked up reliably, the extrema have durations of 4 ms to 8 ms.
- *QRS duration.* Most of the calibration ECGs have a "long" QRS duration of 100 ms (close to the regular QRS duration of adult ECGs). These ECGs have biphasic QRS complexes with either a QR or RS configuration. Another group of calibration ECGs has a monophasic QRS configuration (56 ms) with only a Q or R wave. Two calibration ECGs have exceptionally short QRS durations to simulate neonatal ECGs. (Accurate reproduction of this type of ECG verifies the high frequency response of the system.)
- *Complete mathematical description.* The signals were constructed using elementary mathematical functions (first and second degree polynomials and sinusoids). The first and second derivatives of the function segments were bounded ensuring relatively smooth onsets and offsets of the waveforms. However the R and S peaks are not rounded. The intervals and durations of the waveforms were chosen to simulate real ECGs. When different heart rates are simulated the PR and QT intervals were also adjusted.
- *Naming.* A preliminary proposal was worked out for naming of different signals. For MS-DOS compatibility, each name consists of 8 characters starting with "CAL". The other 5 characters are used to describe the signal characteristics.

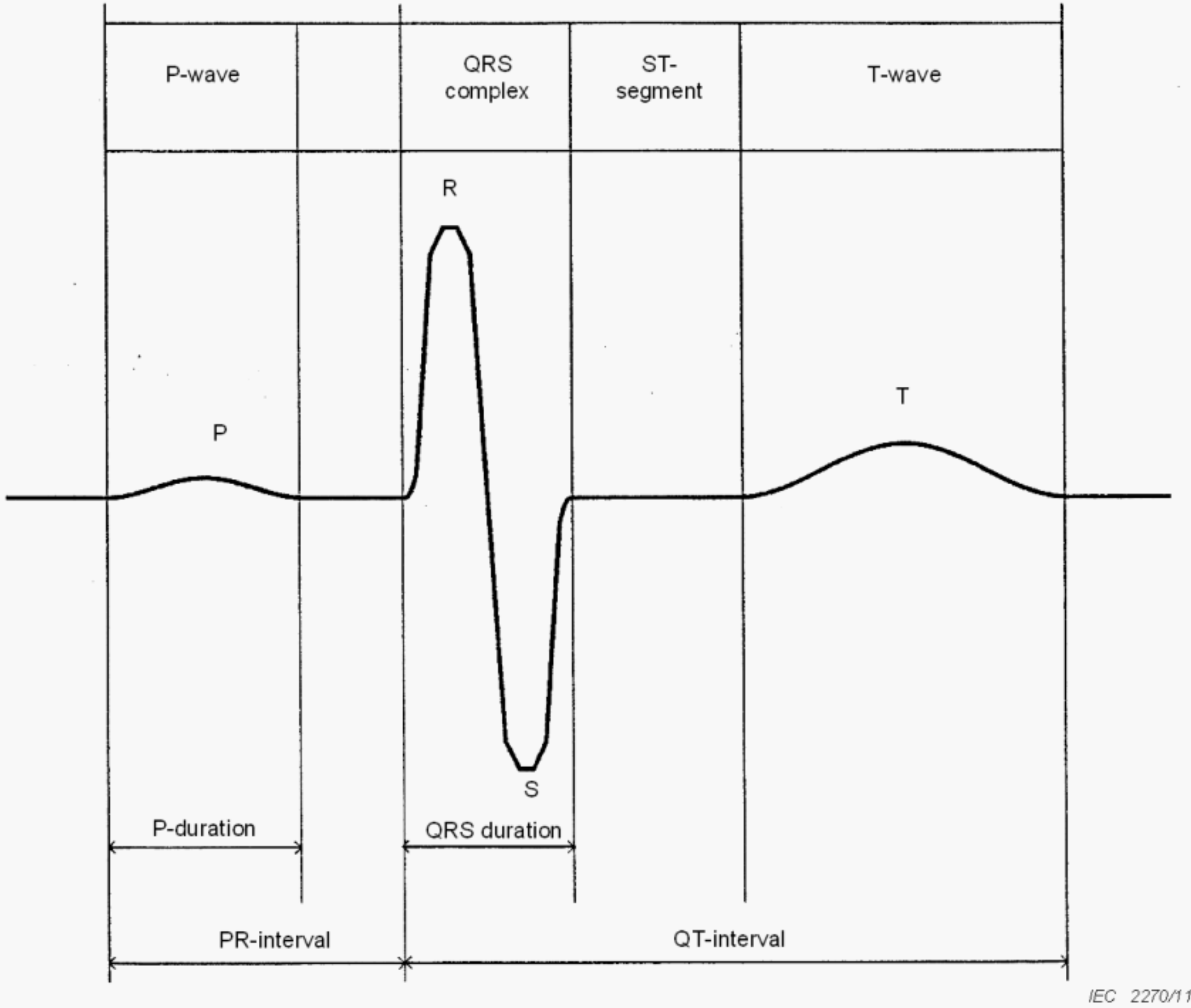


Figure HH.1 – Nomenclature of calibration ECGs

Table HH.1 – Naming of signals (calibration ECGs)

Position	Content	Description
1-3	"CAL"	Identifier for calibration signals
4-5	Number	QRS complex amplitudes (amplitude in mV/10)
6	Number	QRS complex configuration: <div style="display: flex; justify-content: space-between; align-items: center;"> <div>0</div> <div>=</div> <div>RS</div> </div> <div style="display: flex; justify-content: space-between; align-items: center;"> <div>1</div> <div>=</div> <div>R</div> </div> <div style="display: flex; justify-content: space-between; align-items: center;"> <div>2</div> <div>=</div> <div>Q</div> </div> <div style="display: flex; justify-content: space-between; align-items: center;"> <div>3</div> <div>=</div> <div>QR</div> </div> <div style="display: flex; justify-content: space-between; align-items: center;"> <div>4</div> <div>=</div> <div>QRS</div> </div> <div style="display: flex; justify-content: space-between; align-items: center;"> <div>5</div> <div>=</div> <div>short RS</div> </div>
7	Number	ST amplitudes <div style="display: flex; justify-content: space-between; align-items: center;"> <div>0</div> <div>=</div> <div>0 μV</div> </div> <div style="display: flex; justify-content: space-between; align-items: center;"> <div>1</div> <div>=</div> <div>-200 μV</div> </div> <div style="display: flex; justify-content: space-between; align-items: center;"> <div>6</div> <div>=</div> <div>+200 μV</div> </div>
8	Number	Heart rate <div style="display: flex; justify-content: space-between; align-items: center;"> <div>0</div> <div>=</div> <div>60 bpm</div> </div> <div style="display: flex; justify-content: space-between; align-items: center;"> <div>1</div> <div>=</div> <div>40 bpm</div> </div> <div style="display: flex; justify-content: space-between; align-items: center;"> <div>2</div> <div>=</div> <div>120 bpm</div> </div> <div style="display: flex; justify-content: space-between; align-items: center;"> <div>3</div> <div>=</div> <div>150 bpm</div> </div>

At present 16 calibration ECGs are defined (3 are used twice).

a) 7 ECGs test gain factors and linearity:

CAL05000, CAL10000, CAL15000, CAL20000, CAL30000, CAL40000, and CAL50000

These signals are very similar and differ only in the values of the R, S and T amplitudes. A range from $\pm 0,5$ mV up to $\pm 5,0$ mV for the R and S amplitudes and a range from 0,1 mV up to 1,0 mV for the T amplitudes is covered by these signals. This allows testing of the whole amplitude range which ELECTROCARDIOGRAPHS should process.

b) 4 ECGs test for eventual changes in system behaviour due to changes in heart rate:

CAL20000, CAL20002, CAL20500, and CAL20502

Two ECGs are available for each of two heart rates, 60 bpm and 120 bpm. For both ECGs the QRS complex is identical for both heart rates, the PR and QT intervals are adjusted.

c) 2 ECGs test high frequency response performance with high frequency signal components (neonatal ECGs):

CAL20500 and CAL20502

These two ECGs have a very short QRS complex of 36 ms total duration and can serve as simulated neonatal ECGs.

d) 6 ECGs to test low frequency response performance with low frequency signal components (ST elevation/depression):

CAL20100, CAL20110, CAL20160, CAL20200, CAL20210, and CAL20260

Two ECGs, one with only an R wave, the other with only a Q wave, with three different ST segment levels (0 μ V, -200 μ V, +200 μ V) have been designed.

Test Experience. Several ECG systems have been tested with these calibration ECGs. All these systems recognized the calibration signals as ECGs, analyzed them and provided measurements. These results immediately identified malfunctions (overflow in amplifiers, distortions caused by switchable FILTERS, gain accuracy and other effects). In most cases the errors could be attributed to either hardware or to software components of the system.

HH.2.4 Analytical ECGs

To simplify testing of the ECG analysis software, analytical ECGs with waveforms similar to normal ECGs were designed. Figure HH.2 depicts LEAD I and LEAD V2 of an analytical ECG.

These analytical ECGs have similar P, QRS and T shape but are designed for different heart rates with adjusted PR and QT intervals.

These ECGs are designed to analyze whether an ECG program detects precisely the various waveforms. They can also be used to test the interval measurements. With regard to amplitude measurements repeated tests are necessary to eliminate the possible effect of phase shifts during the sampling process.

NOTE Amplitude reproduction is in principle tested by means of the calibration ECGs.

Features of the analytical ECGs are:

- *Biological shapes.* The shapes of the signals are very close to the biological shape, the QRS morphology is like a real normal ECG.
- *Different LEADS.* Each LEAD differs from the other LEADS with respect to wave amplitudes, wave durations, and also wave onsets and offsets as in a real ECG.
- *Different heart rates.* ECGs with four heart rates are provided (40 bpm, 60 bpm, 120 bpm, and 150 bpm). Since the P waves (monophasic and biphasic) as well as the QRS configurations are essentially the same, the behaviour of an analysis program for ECGs at different heart rates can be compared immediately.
- *Complete mathematical description.* All amplitudes and durations are specified sample by sample. During waveform design special care was taken to produce smooth and realistic waveforms and interfaces between the waveforms (no edges, continuous “time derivatives”). Peak amplitudes, wave durations and intervals can be used as references for comparing results obtained from an ELECTROCARDIOGRAPH. In this way these signals can be used to test the “absolute” accuracy of the measuring ELECTROCARDIOGRAPHS since, unlike biosignals, “truth” is known for these the test signals. In particular, systematic measurement errors of the tested system can be detected.
- *Naming.* Each name consists of 8 characters (for MS-DOS compatibility) starting with “ANE”. The names of the signals are specified below.

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

Name	Description
ANE20000	ECG with heart rate of 60 bpm
ANE20001	ECG with heart rate of 40 bpm
ANE20002	ECG with heart rate of 120 bpm
ANE20003	ECG with heart rate of 150 bpm

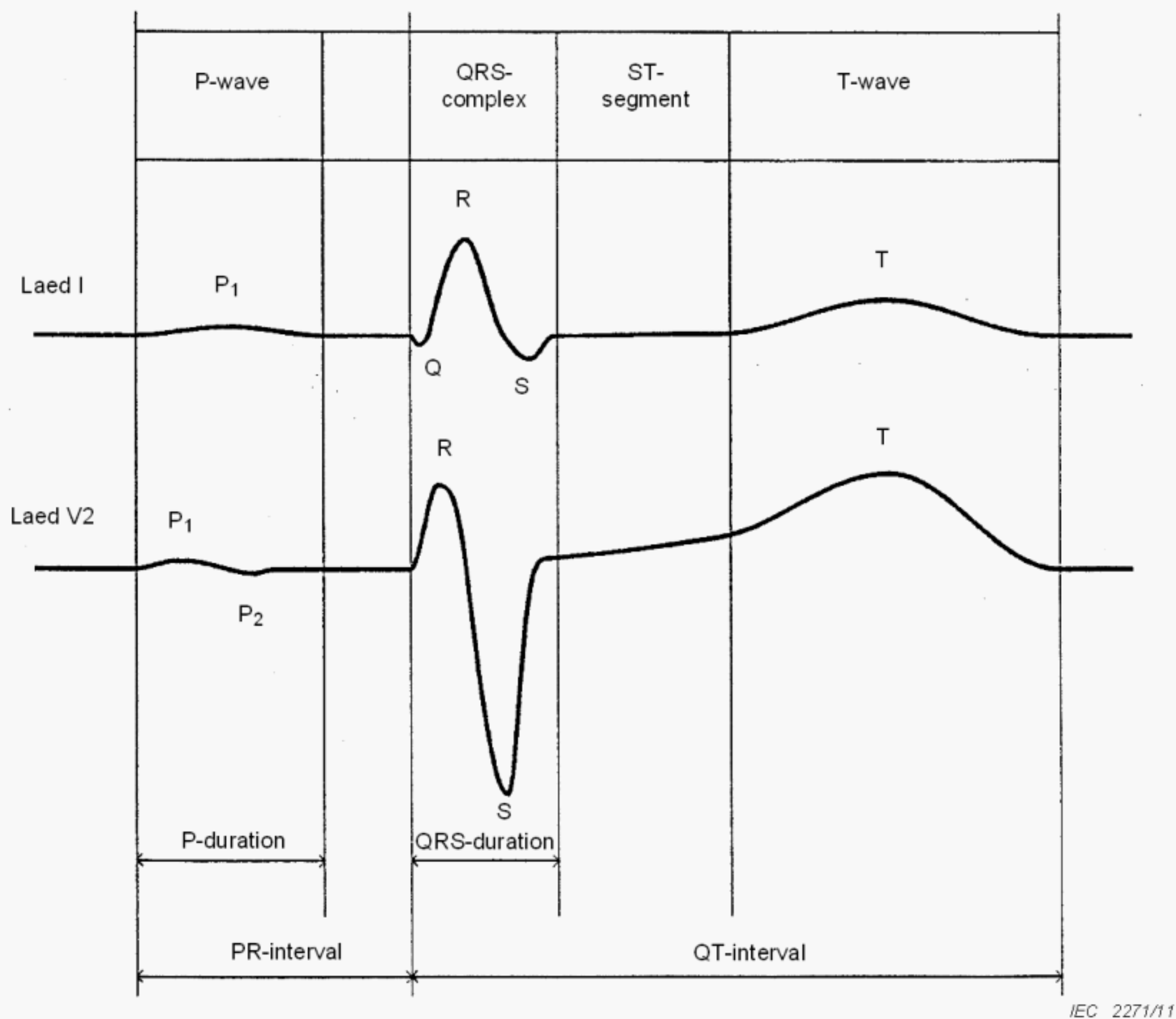


Figure HH.2 – Nomenclature of analytical ECGs

HH.3 Signal characteristics

The following pages depict the calibration and the analytical ECGs.

For each of the ECGs one cycle with the 12 conventional LEADS I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6 is presented.

A detailed table of the reference values for all wave amplitudes and wave durations for each LEAD is also available.

The values for the LEADS III, aVR, aVL, and aVF are derived from the samples itself.

NOTE For the analytical ECGs, the peak amplitudes for these LEADS cannot be determined by the Einthoven equations since the maximum amplitudes in LEAD I and LEAD II do not occur simultaneously.

Amplitude quantisation (1 μ V/LSB – 5 μ V/LSB) and sampling rate (500 samples/s, 1 000 samples/s) cause minor differences in „P-durations“, „PR-intervals“ and „QT-intervals“ if simple amplitude threshold detection criteria used in a wave duration measurement algorithm are applied. Therefore four additional tables with the wave onsets and offsets and with wave durations/intervals are provided for amplitude quantization values of 1 μ V/LSB, 2,5 μ V/LSB and 5 μ V/LSB at sample rates of 1 000 S/s and 500 S/s. These tables follow the detailed reference value table for ANE20002.

For the analytical ECGs the R and s amplitudes in LEADS III, aVR, and aVF differ by 2 μ V between the 1 000 samples/s and the 500 samples/s ECGs, since these peak amplitudes are located at different samples. All other amplitudes and durations are identical.

For the ST segment, various amplitudes (J, ST 20, ST 40, ST 60, ST 80) are given. J point means the QRS end point, and for example “ST 20 amplitude” means the amplitude 20 ms after the J point.

HH.4 List of ECGs

HH.4.1 Calibration ECGs

CAL05000	amplitude calibration, $\pm 0,5$ mV	CAL20200	Q wave, ST = 0 mV
CAL10000	amplitude calibration, $\pm 1,0$ mV	CAL20210	Q wave, ST elevation
CAL15000	amplitude calibration, $\pm 1,5$ mV	CAL20260	Q wave, ST depression
CAL20000	amplitude calibration, $\pm 2,0$ mV, 60 bpm	CAL20500	paediatric, short RS, 60 bpm
CAL20002	amplitude calibration, $\pm 2,0$ mV, 120 bpm	CAL20502	paediatric, short RS, 120 bpm
CAL20100	R wave, ST = 0 mV	CAL30000	amplitude calibration, $\pm 3,0$ mV
CAL20110	R wave, ST elevation	CAL40000	amplitude calibration, $\pm 4,0$ mV
CAL20160	R wave, ST depression	CAL50000	amplitude calibration, $\pm 5,0$ mV

HH.4.2 Analytical ECGs

ANE20000	“normal” ECG wave form, 60 bpm	ANE20002	“normal” ECG wave form, 120 bpm
ANE20001	“normal” ECG wave form, 40 bpm		

CALIBRATION ECG – **CAL05000** – REFERENCE VALUES

GLOBAL INTERVALS

P DURATION	116	P-R INTERVAL	178
QRS DURATION	100	Q-T INTERVAL	394
HEART RATE	60	SAMPLING RATE	500

DURATIONS IN MS

AMPLITUDES IN μV (2,5 μV quantisation)

LEAD	I	II	III	aVR	aVL	aVF
P MEASUREMENTS						
P1 DURATION	116	116	0	116	112	112
P1 AMPLITUDE	150	150	0	-150	75	75
P2 DURATION	0	0	0	0	0	0
P2 AMPLITUDE	0	0	0	0	0	0
QRS MEASUREMENTS/CONF.	RS	RS	–	QR	RS	RS
Q DURATION	0	0	0	50	0	0
Q AMPLITUDE	0	0	0	-500	0	0
R DURATION	50	50	0	50	50	50
R AMPLITUDE	500	500	0	500	250	250
S DURATION	50	50	0	0	50	50
S AMPLITUDE	-500	-500	0	0	-250	-250
QRS DURATION	100	100	0	100	100	100
ST-T MEASUREMENTS, J-POINT = QRS-END						
J AMPLITUDE	0	0	0	0	0	0
ST 20 AMPLITUDE	0	0	0	0	0	0
ST 40 AMPLITUDE	0	0	0	0	0	0
ST 60 AMPLITUDE	0	0	0	0	0	0
ST 80 AMPLITUDE	0	0	0	0	0	0
T AMPLITUDE	100	100	0	-100	50	50
LEAD	V1	V2	V3	V4	V5	V6
P MEASUREMENTS						
P1 DURATION	116	116	116	116	116	116
P1 AMPLITUDE	150	150	150	150	150	150
P2 DURATION	0	0	0	0	0	0
P2 AMPLITUDE	0	0	0	0	0	0
QRS MEASUREMENTS/CONF.	RS	RS	RS	RS	RS	RS
Q DURATION	0	0	0	0	0	0
Q AMPLITUDE	0	0	0	0	0	0
R DURATION	50	50	50	50	50	50
R AMPLITUDE	500	500	500	500	500	500
S DURATION	50	50	50	50	50	50
S AMPLITUDE	-500	-500	-500	-500	-500	-500
QRS DURATION	100	100	100	100	100	100
ST-T MEASUREMENTS, J-POINT = QRS-END						
J AMPLITUDE	0	0	0	0	0	0
ST 20 AMPLITUDE	0	0	0	0	0	0
ST 40 AMPLITUDE	0	0	0	0	0	0
ST 60 AMPLITUDE	0	0	0	0	0	0
ST 80 AMPLITUDE	0	0	0	0	0	0
T AMPLITUDE	100	100	100	100	100	100

CALIBRATION ECG – CAL10000 – REFERENCE VALUES

GLOBAL INTERVALS

P DURATION	116	P-R INTERVAL	178
QRS DURATION	100	Q-T INTERVAL	396
HEART RATE	60	SAMPLING RATE	500

DURATIONS IN MS

AMPLITUDES IN μ V (2,5 μ V quantisation)

LEAD	I	II	III	aVR	aVL	aVF
P MEASUREMENTS						
P1 DURATION	116	116	0	116	112	112
P1 AMPLITUDE	150	150	0	–150	75	75
P2 DURATION	0	0	0	0	0	0
P2 AMPLITUDE	0	0	0	0	0	0
QRS MEASUREMENTS/CONF.						
	RS	RS	–	QR	RS	RS
Q DURATION	0	0	0	50	0	0
Q AMPLITUDE	0	0	0	–1 000	0	0
R DURATION	50	50	0	50	50	50
R AMPLITUDE	1 000	1 000	0	1 000	500	500
S DURATION	50	50	0	0	50	50
S AMPLITUDE	–1 000	–1 000	0	0	–500	–500
QRS DURATION	100	100	0	100	100	100
ST-T MEASUREMENTS, J-POINT = QRS-END						
J AMPLITUDE	0	0	0	0	0	0
ST 20 AMPLITUDE	0	0	0	0	0	0
ST 40 AMPLITUDE	0	0	0	0	0	0
ST 60 AMPLITUDE	0	0	0	0	0	0
ST 80 AMPLITUDE	0	0	0	0	0	0
T AMPLITUDE	200	200	0	–200	100	100

LEAD	V1	V2	V3	V4	V5	V6
P MEASUREMENTS						
P1 DURATION	116	116	116	116	116	116
P1 AMPLITUDE	150	150	150	150	150	150
P2 DURATION	0	0	0	0	0	0
P2 AMPLITUDE	0	0	0	0	0	0
QRS MEASUREMENTS/CONF.						
	RS	RS	RS	RS	RS	RS
Q DURATION	0	0	0	0	0	0
Q AMPLITUDE	0	0	0	0	0	0
R DURATION	50	50	50	50	50	50
R AMPLITUDE	1 000	1 000	1 000	1 000	1 000	1 000
S DURATION	50	50	50	50	50	50
S AMPLITUDE	–1 000	–1 000	–1 000	–1 000	–1 000	–1 000
QRS DURATION	100	100	100	100	100	100
ST-T MEASUREMENTS, J-POINT = QRS-END						
J AMPLITUDE	0	0	0	0	0	0
ST 20 AMPLITUDE	0	0	0	0	0	0
ST 40 AMPLITUDE	0	0	0	0	0	0
ST 60 AMPLITUDE	0	0	0	0	0	0
ST 80 AMPLITUDE	0	0	0	0	0	0
T AMPLITUDE	200	200	200	200	200	200

CALIBRATION ECG – **CAL15000** – REFERENCE VALUES

GLOBAL INTERVALS

P DURATION	116	P-R INTERVAL	178
QRS DURATION	100	Q-T INTERVAL	398
HEART RATE	60	SAMPLING RATE	500

DURATIONS IN MS

AMPLITUDES IN μ V (2,5 μ V quantisation)

LEAD	I	II	III	aVR	aVL	aVF
P MEASUREMENTS						
P1 DURATION	116	116	0	116	112	112
P1 AMPLITUDE	150	150	0	–150	75	75
P2 DURATION	0	0	0	0	0	0
P2 AMPLITUDE	0	0	0	0	0	0
QRS MEASUREMENTS/CONF.						
Q DURATION	0	0	0	50	0	0
Q AMPLITUDE	0	0	0	–1 500	0	0
R DURATION	50	50	0	50	50	50
R AMPLITUDE	1 500	1 500	0	1 500	750	750
S DURATION	50	50	0	0	50	50
S AMPLITUDE	–1 500	–1 500	0	0	–750	–750
QRS DURATION	100	100	0	100	100	100
ST-T MEASUREMENTS, J-POINT = QRS-END						
J AMPLITUDE	0	0	0	0	0	0
ST 20 AMPLITUDE	0	0	0	0	0	0
ST 40 AMPLITUDE	0	0	0	0	0	0
ST 60 AMPLITUDE	0	0	0	0	0	0
ST 80 AMPLITUDE	0	0	0	0	0	0
T AMPLITUDE	300	300	0	–300	150	150
LEAD	V1	V2	V3	V4	V5	V6
P MEASUREMENTS						
P1 DURATION	116	116	116	116	116	116
P1 AMPLITUDE	150	150	150	150	150	150
P2 DURATION	0	0	0	0	0	0
P2 AMPLITUDE	0	0	0	0	0	0
QRS MEASUREMENTS/CONF.						
Q DURATION	0	0	0	0	0	0
Q AMPLITUDE	0	0	0	0	0	0
R DURATION	50	50	50	50	50	50
R AMPLITUDE	1 500	1 500	1 500	1 500	1 500	1 500
S DURATION	50	50	50	50	50	50
S AMPLITUDE	–1 500	–1 500	–1 500	–1 500	–1 500	–1 500
QRS DURATION	100	100	100	100	100	100
ST-T MEASUREMENTS, J-POINT = QRS-END						
J AMPLITUDE	0	0	0	0	0	0
ST 20 AMPLITUDE	0	0	0	0	0	0
ST 40 AMPLITUDE	0	0	0	0	0	0
ST 60 AMPLITUDE	0	0	0	0	0	0
ST 80 AMPLITUDE	0	0	0	0	0	0
T AMPLITUDE	300	300	300	300	300	300

CALIBRATION ECG – CAL20000 – REFERENCE VALUES

GLOBAL INTERVALS

P DURATION	116	P-R INTERVAL	178
QRS DURATION	100	Q-T INTERVAL	398
HEART RATE	60	SAMPLING RATE	500

DURATIONS IN MS

AMPLITUDES IN μ V (2,5 μ V quantisation)

LEAD	I	II	III	aVR	aVL	aVF
P MEASUREMENTS						
P1 DURATION	116	116	0	116	112	112
P1 AMPLITUDE	150	150	0	–150	75	75
P2 DURATION	0	0	0	0	0	0
P2 AMPLITUDE	0	0	0	0	0	0
QRS MEASUREMENTS/CONF.						
	RS	RS	–	QR	RS	RS
Q DURATION	0	0	0	50	0	0
Q AMPLITUDE	0	0	0	–2 000	0	0
R DURATION	50	50	0	50	50	50
R AMPLITUDE	2 000	2 000	0	2 000	1 000	1 000
S DURATION	50	50	0	0	50	50
S AMPLITUDE	–2 000	–2 000	0	0	–1 000	–1 000
QRS DURATION	100	100	0	100	100	100
ST-T MEASUREMENTS, J-POINT = QRS-END						
J AMPLITUDE	0	0	0	0	0	0
ST 20 AMPLITUDE	0	0	0	0	0	0
ST 40 AMPLITUDE	0	0	0	0	0	0
ST 60 AMPLITUDE	0	0	0	0	0	0
ST 80 AMPLITUDE	0	0	0	0	0	0
T AMPLITUDE	400	400	0	–400	200	200
LEAD	V1	V2	V3	V4	V5	V6
P MEASUREMENTS						
P1 DURATION	116	116	116	116	116	116
P1 AMPLITUDE	150	150	150	150	150	150
P2 DURATION	0	0	0	0	0	0
P2 AMPLITUDE	0	0	0	0	0	0
QRS MEASUREMENTS/CONF.						
	RS	RS	RS	RS	RS	RS
Q DURATION	0	0	0	0	0	0
Q AMPLITUDE	0	0	0	0	0	0
R DURATION	50	50	50	50	50	50
R AMPLITUDE	2 000	2 000	2 000	2 000	2 000	2 000
S DURATION	50	50	50	50	50	50
S AMPLITUDE	–2 000	–2 000	–2 000	–2 000	–2 000	–2 000
QRS DURATION	100	100	100	100	100	100
ST-T MEASUREMENTS, J-POINT = QRS-END						
J AMPLITUDE	0	0	0	0	0	0
ST 20 AMPLITUDE	0	0	0	0	0	0
ST 40 AMPLITUDE	0	0	0	0	0	0
ST 60 AMPLITUDE	0	0	0	0	0	0
ST 80 AMPLITUDE	0	0	0	0	0	0
T AMPLITUDE	400	400	400	400	400	400

CALIBRATION ECG – CAL20000 – REFERENCE VALUES

GLOBAL INTERVALS

P DURATION	116	P-R INTERVAL	178
QRS DURATION	100	Q-T INTERVAL	398
HEART RATE	60	SAMPLING RATE	500

DURATIONS IN MS

AMPLITUDES IN μ V (2,5 μ V quantisation)

LEAD	I	II	III	aVR	aVL	aVF
P MEASUREMENTS						
P1 DURATION	116	116	0	116	112	112
P1 AMPLITUDE	150	150	0	–150	75	75
P2 DURATION	0	0	0	0	0	0
P2 AMPLITUDE	0	0	0	0	0	0
QRS MEASUREMENTS/CONF.						
	RS	RS	–	QR	RS	RS
Q DURATION	0	0	0	50	0	0
Q AMPLITUDE	0	0	0	–2 000	0	0
R DURATION	50	50	0	50	50	50
R AMPLITUDE	2 000	2 000	0	2 000	1 000	1 000
S DURATION	50	50	0	0	50	50
S AMPLITUDE	–2 000	–2 000	0	0	–1 000	–1 000
QRS DURATION	100	100	0	100	100	100
ST-T MEASUREMENTS, J-POINT = QRS-END						
J AMPLITUDE	0	0	0	0	0	0
ST 20 AMPLITUDE	0	0	0	0	0	0
ST 40 AMPLITUDE	0	0	0	0	0	0
ST 60 AMPLITUDE	0	0	0	0	0	0
ST 80 AMPLITUDE	0	0	0	0	0	0
T AMPLITUDE	400	400	0	–400	200	200
LEAD	V1	V2	V3	V4	V5	V6
P MEASUREMENTS						
P1 DURATION	116	116	116	116	116	116
P1 AMPLITUDE	150	150	150	150	150	150
P2 DURATION	0	0	0	0	0	0
P2 AMPLITUDE	0	0	0	0	0	0
QRS MEASUREMENTS/CONF.						
	RS	RS	RS	RS	RS	RS
Q DURATION	0	0	0	0	0	0
Q AMPLITUDE	0	0	0	0	0	0
R DURATION	50	50	50	50	50	50
R AMPLITUDE	2 000	2 000	2 000	2 000	2 000	2 000
S DURATION	50	50	50	50	50	50
S AMPLITUDE	–2 000	–2 000	–2 000	–2 000	–2 000	–2 000
QRS DURATION	100	100	100	100	100	100
ST-T MEASUREMENTS, J-POINT = QRS-END						
J AMPLITUDE	0	0	0	0	0	0
ST 20 AMPLITUDE	0	0	0	0	0	0
ST 40 AMPLITUDE	0	0	0	0	0	0
ST 60 AMPLITUDE	0	0	0	0	0	0
ST 80 AMPLITUDE	0	0	0	0	0	0
T AMPLITUDE	400	400	400	400	400	400