

American National Standard



ANSI/AAMI/ IEC 60601- 2-25:2011/ (R)2016

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

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

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AAMI

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American National Standards Institute, Inc.

Abstract: Specifies basic safety and essential performance requirements for electrocardiographs for the production of ECG reports for diagnostic purposes. This particular standard does not include the part of electrocardiographs that provide vector loops or ambulatory electrocardiographic equipment covered by IEC 60601-2-47 and cardiac monitors covered by IEC 60601-2-27.

Keywords: ECG, electrocardiograph, medical electrical equipment, ECG report

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Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. For each International Standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the International Standard. NOTE: Documents are sorted by international designation. The code in the US column, “(R)20xx” indicates the year the document was officially reaffirmed by AAMI. E.g., ANSI/AAMI/ISO 10993-4:2002/(R)2009 indicates that 10993-4, originally approved and published in 2002, was reaffirmed without change in 2009.

Other normatively referenced International Standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

International designation	U.S. designation	Equivalency
IEC 60601-1:2005 Technical Corrigendum 1 and 2	ANSI/AAMI ES60601-1:2005/(R)2012 and ANSI/AAMI ES60601-1:2005/A2:2010/(R)2012 ANSI/AAMI ES60601-1:2005/C1:2009/(R)2012 (amdt)	Major technical variations C1 Identical to Corrigendum 1 & 2
IEC 60601-1-11:2010	ANSI/AAMI HA60601-1-11:2011	Major technical variations
IEC 60601-1-2:2007	ANSI/AAMI/IEC 60601-1-2:2007/(R)2012	Identical
IEC 60601-2-2:2009	ANSI/AAMI/IEC 60601-2-2:2009	Identical
IEC 60601-2-4:2010	ANSI/AAMI/IEC 60601-2-4:2010	Identical
IEC 60601-2-16:2008	ANSI/AAMI/IEC 60601-2-16:2008	Identical
IEC 60601-2-19:2009	ANSI/AAMI/IEC 60601-2-19:2009	Identical
IEC 60601-2-20:2009	ANSI/AAMI/IEC 60601-2-20:2009	Identical
IEC 60601-2-21:2009	ANSI/AAMI/IEC 60601-2-21:2009	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:2004/(R)2009	Major technical variations
IEC 60601-2-25:2011	ANSI/AAMI/IEC 60601-2-25:2011	Identical
IEC 60601-2-27:2011	ANSI/AAMI/IEC 60601-2-27:2011	Identical
IEC 60601-2-47:2001	ANSI/AAMI EC38:2007	Major technical variations
IEC 60601-2-50:2009	ANSI/AAMI/IEC 60601-2-50:2009	Identical
IEC 80001-1:2010	ANSI/AAMI/IEC 80001-1:2010	Identical
IEC 80601-2-30:2009 and Technical Corrigendum 1	ANSI/AAMI/IEC 80601-2-30:2009 and ANSI/AAMI/IEC 80601-2-30:2009/C1:2009 (amdt) – consolidated text	Identical (with inclusion) C1 Identical to Corrigendum 1
IEC 80601-2-58:2008	ANSI/AAMI/IEC 80601-2-58:2008	Identical
IEC/TR 60878:2009	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC/TR 61289:2011	ANSI/AAMI/IEC TIR61289:2011	Identical
IEC/TR 62296:2009	ANSI/AAMI/IEC TIR62296:2009	Identical
IEC 62304:2006	ANSI/AAMI/IEC 62304:2006	Identical
IEC/TR 62348:2006	ANSI/AAMI/IEC TIR62348:2006	Identical
IEC/TR 62354:2009	ANSI/AAMI/IEC TIR62354:2009	Identical
IEC 62366:2007	ANSI/AAMI/IEC 62366:2007	Identical
IEC/TR 80002-1:2009	ANSI/IEC/TR 80002-1:2009	Identical
ISO 5840:2005	ANSI/AAMI/ISO 5840:2005/(R)2010	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001/(R)2010	Identical
ISO 7199:2009 and Amendment 1:2012	ANSI/AAMI/ISO 7199:2009 and Amendment 1:2012	Identical
ISO 8637:2010	ANSI/AAMI/ISO 8637:2010	Identical
ISO 8638:2010	ANSI/AAMI/ISO 8638:2010	Identical
ISO 10993-1:2009	ANSI/AAMI/ISO 10993-1:2009	Identical
ISO 10993-2:2006	ANSI/AAMI/ISO 10993-2:2006/(R)2010	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003/(R)2009	Identical
ISO 10993-4:2002 and Amendment 1:2006	ANSI/AAMI/ISO 10993-4:2002/(R)2009 and Amendment 1:2006/(R)2009	Identical
ISO 10993-5:2009	ANSI/AAMI/ISO 10993-5:2009	Identical
ISO 10993-6:2007	ANSI/AAMI/ISO 10993-6:2007/(R)2010	Identical
ISO 10993-7:2008	ANSI/AAMI/ISO 10993-7:2008/(R)2012	Identical
ISO 10993-9:2009	ANSI/AAMI/ISO 10993-9:2009	Identical
ISO 10993-10:2010	ANSI/AAMI/ISO 10993-10:2010	Identical
ISO 10993-11:2006	ANSI/AAMI/ISO 10993-11:2006/(R)2010	Identical
ISO 10993-12:2007	ANSI/AAMI/ISO 10993-12:2007	Identical
ISO 10993-13:2010	ANSI/AAMI/ISO 10993-13:2010	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001/(R)2006	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000/(R)2006	Identical
ISO 10993-16:2010	ANSI/AAMI/ISO 10993-16:2010	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002/(R)2008	Identical
ISO 10993-18:2005	ANSI/AAMI BE83:2006/(R)2011	Major technical variations
ISO/TS 10993-19:2006	ANSI/AAMI/ISO TIR10993-19:2006	Identical
ISO/TS 10993-20:2006	ANSI/AAMI/ISO TIR10993-20:2006	Identical
ISO 11135-1:2007	ANSI/AAMI/ISO 11135-1:2007	Identical

International designation	U.S. designation	Equivalency
ISO/TS 11135-2:2008	ANSI/AAMI/ISO TIR11135-2:2008	Identical
ISO 11137-1:2006	ANSI/AAMI/ISO 11137-1:2006/(R)2010	Identical
ISO 11137-2:2012	ANSI/AAMI/ISO 11137-2:2012	Identical
ISO 11137-3:2006	ANSI/AAMI/ISO 11137-3:2006/(R)2010	Identical
ISO 11138-1:2006	ANSI/AAMI/ISO 11138-1:2006/(R)2010	Identical
ISO 11138-2:2006	ANSI/AAMI/ISO 11138-2:2006/(R)2010	Identical
ISO 11138-3:2006	ANSI/AAMI/ISO 11138-3:2006/(R)2010	Identical
ISO 11138-4:2006	ANSI/AAMI/ISO 11138-4:2006/(R)2010	Identical
ISO 11138-5:2006	ANSI/AAMI/ISO 11138-5:2006/(R)2010	Identical
ISO/TS 11139:2006	ANSI/AAMI/ISO 11139:2006	Identical
ISO 11140-1:2005	ANSI/AAMI/ISO 11140-1:2005/(R)2010	Identical
ISO 11140-3:2007	ANSI/AAMI/ISO 11140-3:2007	Identical
ISO 11140-4:2007	ANSI/AAMI/ISO 11140-4:2007	Identical
ISO 11140-5:2007	ANSI/AAMI/ISO 11140-5:2007	Identical
ISO 11607-1:2006	ANSI/AAMI/ISO 11607-1:2006/(R)2010	Identical
ISO 11607-2:2006	ANSI/AAMI/ISO 11607-2:2006/(R)2010	Identical
ISO 11663:2009	ANSI/AAMI/ISO 11633:2009	Identical
ISO 11737-1:2006	ANSI/AAMI/ISO 11737-1:2006	Identical
ISO 11737-2:2009	ANSI/AAMI/ISO 11737-2:2009	Identical
ISO/TS 12417:2011	ANSI/AAMI/ISO TIR12417:2011	Identical
ISO 13022:2012	ANSI/AAMI/ISO 13022:2012	Identical
ISO 13408-1:2008	ANSI/AAMI/ISO 13408-1:2008/(R)2011	Identical
ISO 13408-2:2003	ANSI/AAMI/ISO 13408-2:2003	Identical
ISO 13408-3:2006	ANSI/AAMI/ISO 13408-3:2006	Identical
ISO 13408-4:2005	ANSI/AAMI/ISO 13408-4:2005	Identical
ISO 13408-5:2006	ANSI/AAMI/ISO 13408-5:2006	Identical
ISO 13408-6:2006	ANSI/AAMI/ISO 13408-6:2006	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003/(R)2009	Identical
ISO 13958:2009	ANSI/AAMI/ISO 13958:2009	Identical
ISO 13959:2009	ANSI/AAMI/ISO 13959:2009	Identical
ISO 14155:2011	ANSI/AAMI/ISO 14155:2011	Identical
ISO 14160:2011	ANSI/AAMI/ISO 14160:2011	Identical
ISO 14161:2009	ANSI/AAMI/ISO 14161:2009	Identical
ISO 14708-3:2008	ANSI/AAMI/ISO 14708-3:2008	Identical
ISO 14708-4:2008	ANSI/AAMI/ISO 14708-4:2008	Identical
ISO 14708-5:2010	ANSI/AAMI /ISO 14708-5:2010	Identical
ISO 14937:2009	ANSI/AAMI/ISO 14937:2009	Identical
ISO/TR 14969:2004	ANSI/AAMI/ISO TIR14969:2004	Identical
ISO 14971:2007	ANSI/AAMI/ISO 14971:2007/(R)2010	Identical
ISO 15223-1:2007 and A1:2008	ANSI/AAMI/ISO 15223-1:2007/(R)2012 and A1:2008/(R)2012	Identical
ISO 15223-2:2010	ANSI/AAMI/ISO 15223-2:2010	Identical
ISO 15225:2010	ANSI/AAMI/ISO 15225:2010	Identical
ISO 15674:2009	ANSI/AAMI/ISO 15674:2009	Identical
ISO 15675:2009	ANSI/AAMI/ISO 15675:2009	Identical
ISO 15882:2008	ANSI/AAMI/ISO 15882:2008	Identical
ISO 15883-1:2006	ANSI/AAMI ST15883-1:2009	Major technical variations
ISO/TR 16142:2006	ANSI/AAMI/ISO TIR16142:2005	Identical
ISO 17664:2004	ANSI/AAMI ST81:2004	Major technical variations
ISO 17665-1:2006	ANSI/AAMI/ISO 17665-1:2006	Identical (with inclusions)
ISO/TS 17665-2:2009	ANSI/AAMI/ISO TIR17665-2:2009	Identical
ISO 18472:2006	ANSI/AAMI/ISO 18472:2006/(R)2010	Identical
ISO/TS 19218-1:2011	ANSI/AAMI/ISO TIR19218:2011	Identical
ISO 20857:2010	ANSI/AAMI/ISO 20857:2010	Identical
ISO 22442-1:2007	ANSI/AAMI/ISO 22442-1:2007	Identical
ISO 22442-2:2007	ANSI/AAMI/ISO 22442-2:2007	Identical
ISO 22442-3:2007	ANSI/AAMI/ISO 22442-3:2007	Identical
ISO/TR 22442-4:2010	ANSI/AAMI/ISO TIR22442-4:2010	Identical
ISO 23500:2011	ANSI/AAMI/ISO 23500:2011	Identical
ISO/TS 23810:2012	ANSI/AAMI/ISO TIR23810:2012	Identical
ISO 25539-1:2003 and A1:2005	ANSI/AAMI/ISO 25539-1:2003/(R)2009 and A1:2005/(R)2009	Identical
ISO 25539-2:2008	ANSI/AAMI/ISO 25539-2:2008	Identical
ISO 25539-3:2011	ANSI/AAMI/ISO 25539-3:2011	Identical
ISO 26722:2009	ANSI/AAMI/ISO 26722:2009	Identical
ISO 27185:2012	ANSI/AAMI/ISO 27185:2012	Identical
ISO 27186:2010	ANSI/AAMI/ISO 27186:2010	Identical
ISO 80369-1:2010	ANSI/AAMI/ISO 80369-1:2010	Identical
ISO 81060-1:2007	ANSI/AAMI/ISO 81060-1:2007	Identical
ISO 81060-2:2009	ANSI/AAMI/ISO 81060-2:2009	Identical

Committee representation

Association for the Advancement of Medical Instrumentation

Electrocardiograph (ECG) Committee

The adoption of IEC 60601-2-25 as a revision of ANSI/AAMI EC11:1991 was initiated by the AAMI ECG Committee, which serves as the U.S. TAG (technical advisory group) for IEC/SC 62D. U.S. representatives played an active role in developing the IEC standard. Committee approval of the standard does not necessarily imply that all committee members voted for its approval.

At the time this document was published, the **AAMI ECG Committee** had the following members:

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Ahmet Turkmen, BS MS PhD
Brian J. Young, GE Healthcare

Members: Robert William Bain, CBET, Baltimore Medical Engineers & Technician Society
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Scott Coggins, Covidien
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NOTE--Participation by federal agency representatives in the development of this document does not constitute endorsement by the federal government or any of its agencies.

Background of ANSI/AAMI adoption of IEC 60601-2-25:2011

As indicated in the foreword to the main body of this document (page x), the International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising of all national electrotechnical committees. The United States is one of the IEC members that took an active role in the development of this standard, which was developed by the IEC Technical Subcommittee 62D, Electromedical equipment, maintenance team (MT) 22 on Electromedical diagnostic and patient monitoring equipment.

U.S. participation in IEC/SC 62D is organized through the U.S. Technical Advisory Group for IEC/SC 62D, administered by the Association for the Advancement of Medical Instrumentation (AAMI) on behalf of the U.S. National Committee of the American National Standards Institute. The U.S. made a considerable contribution to this International Standard.

AAMI encourages its committees to harmonize their work with International Standards to the extent possible. Upon review of the final draft International Standard of IEC 60601-2-25:2011, the AAMI ECG Committee, which serves as the U.S. Technical Advisory sub-Group to IEC/SC 62D, decided to adopt it verbatim as a revision of ANSI/AAMI EC11:1991.

AAMI and ANSI procedures require that standards be reviewed every five years and, if necessary, revised to reflect technological advances that may have occurred since publication.

AAMI (and ANSI) have adopted other IEC and ISO standards. See the Glossary of Equivalent Standards for a list of IEC and ISO standards adopted by AAMI, which gives the corresponding U.S. designation and the level of equivalency with the IEC and ISO standard.

The concepts incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as advances are made in technology and as new data come to light.

This standard reflects the conscientious efforts of concerned health care professionals and medical device manufacturers to develop a standard for those performance levels that can be reasonably achieved at this time.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

NOTE-This background does not contain provisions of the American National Standard, *Medical electrical equipment – Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs* (ANSI/AAMI/IEC 60601-2-25:2011), but it does provide important information about the development and intended use of the document.

NOTE-Beginning with the foreword on page x, this American National Standard is identical to IEC 60601-2-25:2011.

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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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.

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

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:

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 92.

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 an 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 favorable 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

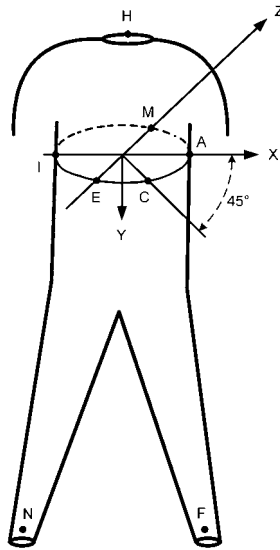
In order to minimize the possibility of incorrect connections, the PATIENT CABLE shall be permanently marked with one of the identifiers (ELECTRODE identifier and/or color code) specified in Table 201.102;

Detachable LEAD WIRES shall be permanently marked on both ends with the identifiers (ELECTRODE identifier and/or color 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 color code

LEAD-System	CODE 1 (usually European)		CODE 2 (usually American)		Position on body surface
	ELECTRODE identifier	Color code	ELECTRODE identifier	Color 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.					



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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 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 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.

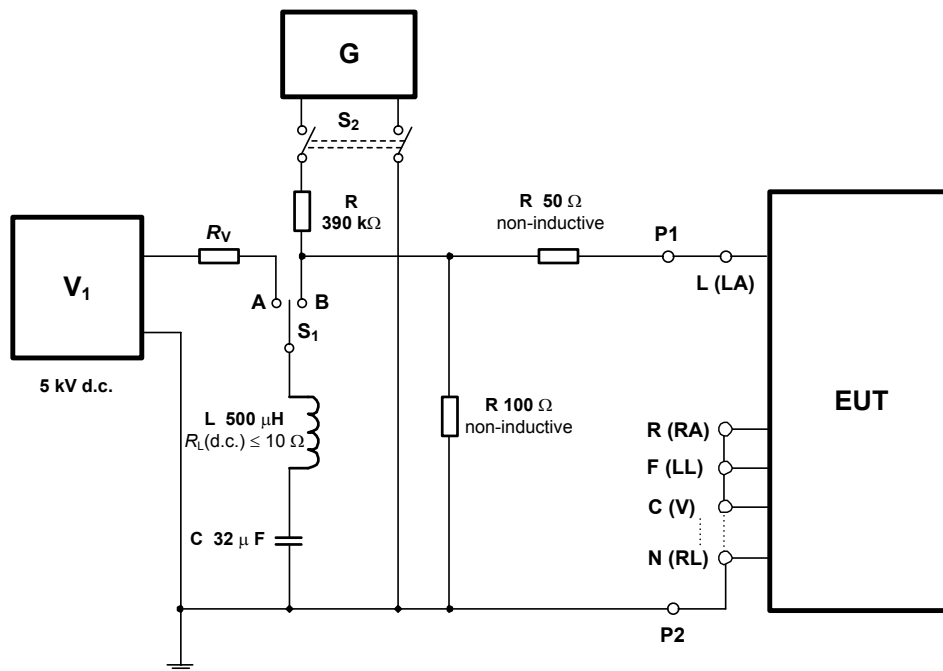
Table 201.103 – Protection against the effect of defibrillation (test conditions)

	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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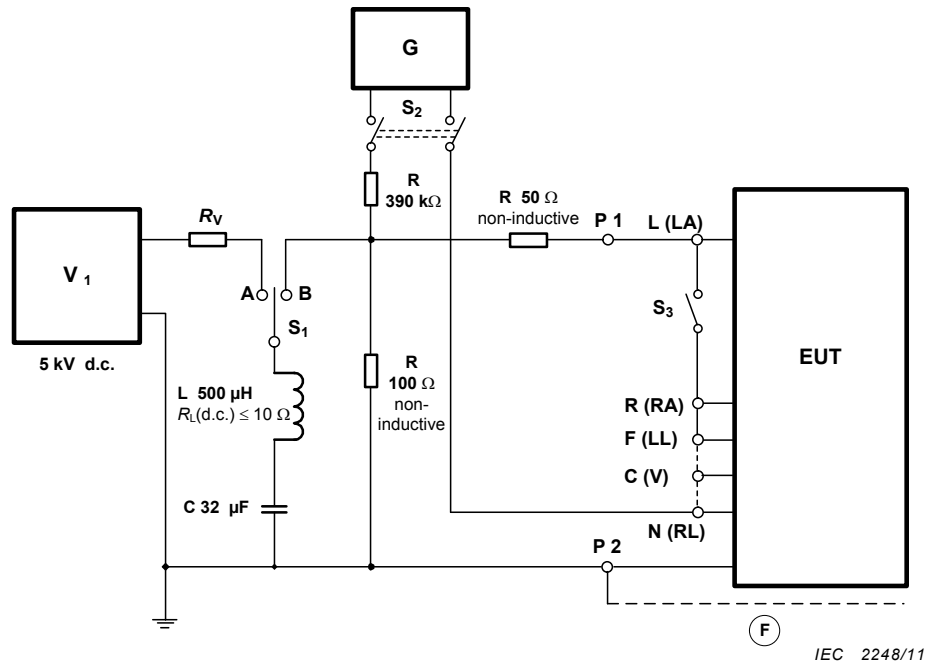
Components

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

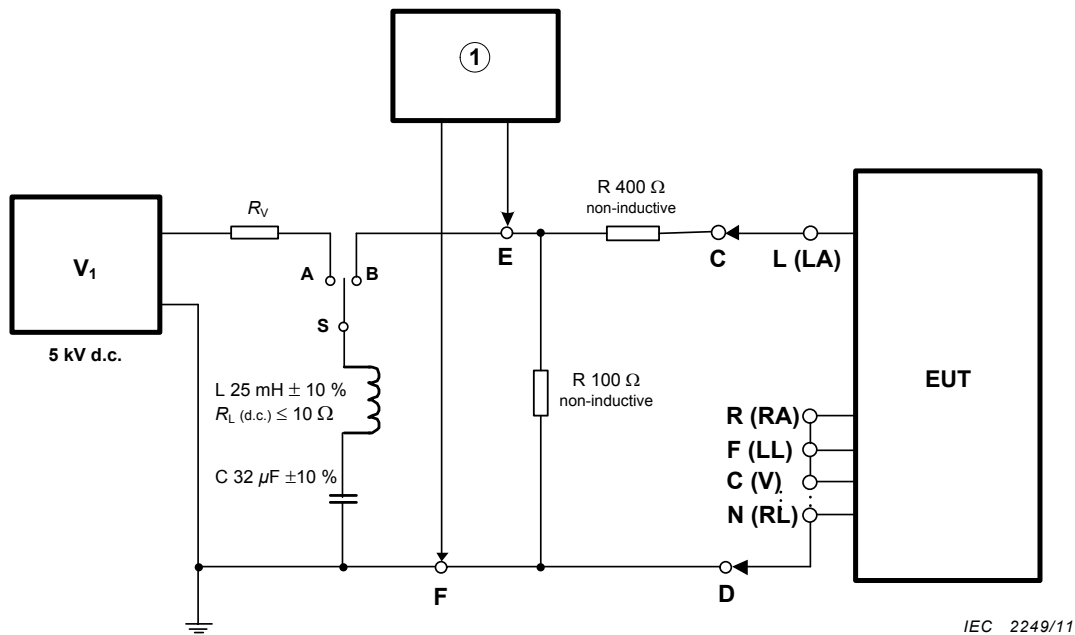
- G Sine wave generator 20 V peak-to-valley of 10 Hz
- V₁ High voltage source 5 kV d.c.
- Ⓢ Switch; max. load 60 A, 5 kV
- S₂ Switch connecting the signal source, 5 kV
- S₃ Switch applying the signal source to LEAD WIRES
- R_L d.c. resistance of inductance L
- R_V Current limiting resistor
- P1 Connecting 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 analog format, perform this test five times. Calculate the differences between measurements and reference values of the five tests.

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

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

201.12.1.101.3 Requirements for interval measurements

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

201.12.1.101.3.1 * Requirements for absolute interval and wave duration measurements

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

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

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

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

If these ECGs are fed into the ELECTROCARDIOGRAPH in analog 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 analog or digital format and let them be analyzed (see guidelines at the end of Annex AA for inputting ECGs). Determine the differences between the interval measurements and the reference values.

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

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

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

201.12.4 Protection against hazardous output

Additional subclauses:

201.12.4.101 * Indication of inoperable ELECTROCARDIOGRAPH

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

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

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

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

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

The indicating device shall be fully operative before the amplitude of the 10 Hz signal is reduced to 5 mm (0.5 mV referred to the input).

201.12.4.102 LEADS

201.12.4.102.1 LEAD representation, nomenclature and definition

In a rectangular coordinate system, increasing time is in the positive x-direction and the positive deflection of the trace is in the positive y-direction when a polarized 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