

American National Standard



ANSI/AAMI/ IEC 60601- 2-27:2011/ (R)2016

Medical electrical
equipment — Part 2-27:
Particular requirements
for the basic safety and
essential performance
of electrocardiographic
monitoring equipment

Medical electrical equipment — Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment

Approved 8 December 2010 by
AAMI

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American National Standards Institute, Inc.

Abstract: This standard specifies basic safety requirements and essential performance for electrocardiographic (ECG) monitoring equipment. It is applicable to ECG monitoring equipment used in a hospital environment. If it is used outside the hospital environment, such as in ambulances and air transport, the ECG monitoring equipment shall comply with this standard. This standard is not applicable to electrocardiographic monitors for home use and ECG telemetry systems. However, manufacturers should consider using relevant clauses of this standard as appropriate for their intended use/intended purpose. Ambulatory ("Holter") monitors, fetal heart rate monitors, pulse plethysmographic devices, and other ECG recording equipment are outside the scope of this particular standard.

Keywords: electromedical equipment, ECG, monitors, medical electrical equipment

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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 and ANSI/AAMI ES60601-1:2005/A2:2010 ANSI/AAMI ES60601-1:2005/C1:2009 (amdt)	Major technical variations C1 Identical to Corrigendum 1 & 2
IEC 60601-1-2:2007	ANSI/AAMI/IEC 60601-1-2:2007	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 60601-2-27:2011	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 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	ANSI/AAMI/ISO 7199:2009	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	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	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 11137-2:2006 (2006-08-01 corrected)	ANSI/AAMI/ISO 11137-2:2006	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 11663:2009	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 13408-1:2008	ANSI/AAMI/ISO 13408-1:2008	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 14160:1998	ANSI/AAMI/ISO 14160:1998/(R)2008	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 and A1:2008	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 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 26722:2009	ANSI/AAMI/ISO 26722:2009	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 60601-2-27 as a revision of ANSI/AAMI EC13:2002/(R)2007 was initiated by the AAMI ECG/Cardiac Monitor and Diagnostic ECG Working Group of the AAMI ECG Committee. 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:

Cochairs Carl A. Pantiskas
Ahmet Turkmen, BS MS PhD

Members: Arthur R. Eddy, Jr.
Luis A. Melendez, Partners Healthcare
George Moody, Massachusetts Institute of Technology
Carl A. Pantiskas, Draeger Medical Systems Inc.
Jonathan Steinberg, MD, St Lukes Roosevelt Hospital Center
Richard A. Sunderland, Welch Allyn, Inc.
Ahmet Turkmen, BS MS PhD, University of Wisconsin-Stout
Brian J. Young, GE Healthcare
Sophia Zhou, PhD FACC, Philips Electronics North America

The **AAMI EC/Cardiac Monitor and Diagnostic ECG Working Group** had the following members:

Cochairs: Luis A. Melendez
Richard A. Sunderland

Members: Sreeram Dhurjaty, Dhurjaty Electronics Consulting LLC
Richard Diefes, ECRI Institute
Greg Downs, Spacelabs Medical Inc.
James J. Greco, Medapprove Inc.
David G. Hernke, MSEE, GE Healthcare
Charles S. Ho, PhD, FDA/CDRH
Dongping Lin, PhD
Luis A. Melendez, Partners Healthcare
William J. Murray, MS, Draeger Medical Systems Inc.
Robert Nelson, Hospira Worldwide Inc.
Cadathur Rajagopalan, PhD SMIEEE, Mindray DS USA Inc.
Richard A. Sunderland, Welch Allyn Inc.
Ahmet Turkmen, BS MS PhD, University of Wisconsin-Stout
John Wang, Philips Electronics North America

Alternates: Steve Baker, PhD, Welch Allyn, Inc.
Carl A. Pantiskas, Draeger Medical Systems Inc.
Shankara B. Reddy, PhD FACC, Philips Electronics North America
Donald Stewart, Spacelabs Medical Inc.
Brian J. Young, GE Healthcare

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 60601-2-27:2011

As indicated in the foreword to the main body of this document (page ix), the International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprised 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 60601-2-27:2011, the AAMI EC/WG 04, Cardiac Monitor and Diagnostic ECG Working Group of the AAMI ECG Committee, which serves as the U.S. Technical Advisory sub-Group to MT22, decided to adopt it verbatim as a revision of ANSI/AAMI EC13:2002/(R)2007.

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 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment* (ANSI/AAMI/IEC 60601-2-27:2011), but it does provide important information about the development and intended use of the document.

NOTE—Beginning with the foreword on page ix, this American National Standard is identical to IEC 60601-2-27:2011.

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT —

Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment

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 60601-2-27 has been prepared by IEC subcommittee 62D: Electromedical equipment of IEC technical committee 62: Electrical equipment in medical practice.

This third edition cancels and replaces the second edition of IEC 60601-2-27 published in 2005. This edition constitutes a technical revision to the new structure of IEC 60601-1:2005 (third edition).

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

FDIS	Report on voting
62D/900/FDIS	62D/913/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.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.

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 MONITORING 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.

The aim of this third edition is to bring this particular standard up to date with reference to the third edition of the general standard through reformatting and technical changes.

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. It is considered that knowledge of the reasons for these requirements will not only facilitate the 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 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment****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 BASIC SAFETY and ESSENTIAL PERFORMANCE of ELECTROCARDIOGRAPHIC (ECG) MONITORING EQUIPMENT as defined in 201.3.63 and hereinafter also referred to as ME EQUIPMENT. This particular standard applies to ME EQUIPMENT used in a hospital environment as well as when used outside the hospital environment, such as in ambulances and air transport. This particular standard also applies to ECG telemetry systems used in a hospital environment.

ME EQUIPMENT intended for use under extreme or uncontrolled environmental conditions outside the hospital environment, 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.

This standard is not applicable to electrocardiographic monitors for home use. However, MANUFACTURERS should consider using relevant clauses of this standard as appropriate for their INTENDED USE.

Ambulatory ("Holter") monitors, fetal heart rate monitoring, pulse plethysmographic devices, and other ECG recording equipment are outside the scope of this particular standard.

201.1.2 Object

Replacement:

The object of this particular standard is to establish BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for ELECTROCARDIOGRAPHIC (ECG) MONITORING EQUIPMENT 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 60601-1-2:2007 and IEC 60601-1-8:2006 apply as modified in Clauses 202 and 208 respectively. IEC 60601-1-3 does 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 IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 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, 203 for IEC 60601-1-3, 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

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*

IEC 60601-1-8:2008, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

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*

IEC 60601-2-25:____²⁾ *Medical electrical equipment – Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs*

IEC 60601-2-49____³⁾, *Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment*

NOTE Informative references are listed in the bibliography beginning on page 68.

201.3 Terms and definitions

NOTE An index of defined terms is found beginning on page 69.

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

Replacement:

²⁾ Second edition, to be published.

³⁾ Second edition, to be published.

201.3.63

ELECTROCARDIOGRAPHIC (ECG) MONITORING EQUIPMENT ME EQUIPMENT

device including ELECTRODES, LEAD WIRES and interconnecting means for the monitoring and/or recording of heart action potentials from one PATIENT and displaying the resultant data

NOTE An ECG telemetry transmitter and receiver including its associated display of one PATIENT'S data forms an ME EQUIPMENT. ECG telemetry is typically used to display that data of a PATIENT at a remote location. Implementations of these remote displays frequently display data from several PATIENTS at the same time, but logically separate the data of each PATIENT on such a display.

Additional definitions:

201.3.201

COMMON MODE REJECTION (CMR)

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

201.3.202

ELECTRODE

sensor in contact with a specified part of the body to detect electrical cardiac activity

201.3.203

ELECTROCARDIOGRAM (ECG)

graphical presentation of one or more LEADS over time

201.3.204

GAIN

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

NOTE GAIN is expressed in mm/mV

201.3.205

GAIN INDICATOR

graphical indication on a PERMANENT DISPLAY or NON-PERMANENT DISPLAY that allows the clinical OPERATOR to visually estimate the amplitude of the ECG input signal

201.3.206

LEAD

voltage between ELECTRODES

201.3.207

LEAD SELECTOR

system to select certain LEADS

201.3.208

LEAD WIRE

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

201.3.209

NEUTRAL ELECTRODE

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

NOTE A NEUTRAL ELECTRODE is sometimes referred to as a reference ELECTRODE.

201.3.210

NOISE

unwanted signals of any frequency present in the ELECTROCARDIOGRAM

201.3.211

NON-PERMANENT DISPLAY

a non-persistent presentation of an ELECTROCARDIOGRAM (ECG)

NOTE An example of NON-PERMANENT DISPLAY is a LCD screen across which an ECG waveform is moving or a transient presentation of an ECG waveform.

201.3.212

PATIENT CABLE

multiwire cable used to connect LEAD WIRES to ME EQUIPMENT

201.3.213

PERMANENT DISPLAY

a persistent presentation of an ELECTROCARDIOGRAM (ECG)

NOTE Examples of PERMANENT DISPLAYS are hardcopy printouts of an ECG.

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

Additional ESSENTIAL PERFORMANCE requirements for ELECTROCARDIOGRAPHIC MONITORING EQUIPMENT are found in the subclauses listed in Table 201.101

Table 201.101 – ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
Defibrillator protection	201.8.5.5.1
Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT	201.11.8
Protection against depletion of battery	201.11.8.101
ESSENTIAL PERFORMANCE of ME EQUIPMENT	201.12.1.101
Electrosurgery interference	202.6.2.101
Time to alarm for heart rate ALARM CONDITIONS	208.6.6.2.103
TECHNICAL ALARM CONDITIONS indicating inoperable ME EQUIPMENT	208.6.6.2.104

201.5 General requirements for testing of ME EQUIPMENT

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

201.5.4 Other conditions

Addition:

Unless otherwise stated, tests shall be carried out with the ACCESSORIES and the recording materials specified by the MANUFACTURER.

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.

The values used in test circuits, unless otherwise specified, shall have at least an accuracy as given below:

- resistors: $\pm 1\%$;
- capacitors: $\pm 10\%$;
- inductors: $\pm 10\%$;
- test voltages: $\pm 1\%$

201.5.8 *Sequence of tests

Amendment:

Tests called for in 201.8.5.5.1 of this particular standard and in 8.5.5 of the general standard shall be carried out prior to the LEAKAGE CURRENT and dielectric strength tests described in subclauses 8.7 and 8.8 of the general standard and prior to the tests specified in subclauses 201.11.6.5 and 201.12.1.101 of this particular standard. The tests for subclauses 201.12.1.101.7, 201.12.1.101.9 and 201.12.1.101.16 b) shall be performed (in that order) before the tests for the remaining subclauses of 201.12.1.101 are performed.

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 (see 7.2.11 of the general standard).

201.7 ME EQUIPMENT identification, marking and documents

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

201.7.2.4 ACCESSORIES

Addition:

201.7.2.4.101 Marking of LEAD WIRES

In order to minimize the possibility of incorrect connections the PATIENT CABLE where the LEAD WIRES are connected shall be permanently marked with at least one of the identifiers (ELECTRODE identifier and/or color code) specified in Table 201.102. Both ends of detachable LEAD WIRES shall be permanently marked with the same identifiers.

Table 201.102 – ELECTRODES and NEUTRAL ELECTRODE, their position, identification and color

LEAD System	Code 1 (usually European)		Code 2 (usually American)		ELECTRODE position on body surface
	ELECTRODE Identifier	ELECTRODE Color code	ELECTRODE Identifier	ELECTRODE 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	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 the front midline and left midaxillary line of 45 degrees
	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 ELECTRODE)
^a Located at the transverse level of the ventricles, if known, or otherwise at the fifth intercostal space					

201.7.9.2.9 Operating instructions

Addition:

201.7.9.2.9.101 Additional instructions for use

a) The operating instructions shall include the following:

- 1) the INTENDED USE including the environment of use;
- 2) that conductive parts of ELECTRODES and associated connectors for APPLIED PARTS, including the NEUTRAL ELECTRODE, should not contact any other conductive parts including earth;
- 3) instructions for connecting a POTENTIAL EQUALIZATION CONDUCTOR, if applicable;
- 4) * 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;

- 5) advice to the clinical OPERATOR regarding whether the ME EQUIPMENT incorporates means to protect the PATIENT against burns when used with HIGH-FREQUENCY (HF) SURGICAL EQUIPMENT. Advice shall be given regarding the location of ELECTRODES and LEAD WIRES etc, to reduce the hazards of burns in the event of a defect in the neutral electrode connection of the HF SURGICAL EQUIPMENT;

NOTE "Neutral electrode" here refers to a term defined in 201.3.227 of IEC 60601-2-2.

- 6) the choice and application of specified PATIENT CABLES and LEAD WIRES; the choice and application of ELECTRODES;
- 7) * advice regarding testing of the ME EQUIPMENT and ACCESSORIES on a daily basis (by the clinical OPERATOR) and on a scheduled basis (as a service activity). Emphasis should be placed on how the clinician may test visual and auditory ALARM SIGNALS;
- 8) explanation of TECHNICAL ALARM CONDITIONS (see 208.6.8.101);
- 9) explanation of how the heart-rate value may be affected by the operation of cardiac pacemaker pulses or by cardiac arrhythmias;
- 10) the default settings (e.g. ALARM SETTINGS, modes, and filter);
- 11) the configuration procedure that allows the ALARM SIGNAL inactivation states (ALARM PAUSED, AUDIO PAUSED, ALARM OFF, AUDIO OFF) and the function ALARM RESET to be controlled remotely (see 208.6.11.101), if provided;
- 12) 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 difficulties, not to technical malfunctions.

- 13) the amplitude, pulse width, and overshoot of pacemaker pulses that are rejected by the ME EQUIPMENT (see 201.12.1.101.13);
- 14) the subsequent operation of the ME EQUIPMENT after interruption of SUPPLY MAINS exceeding 30 s (see 201.11.8);
- 15) description of how to disable ALARM SIGNALS for TECHNICAL ALARM CONDITIONS if LEAD WIRES or modules are intentionally disconnected by the clinical OPERATOR;
- 16) advice on the preferred ALARM SETTINGS and configurations of the ALARM SYSTEM when its INTENDED USE includes the monitoring of PATIENTS that are not continuously attended by a clinical OPERATOR.

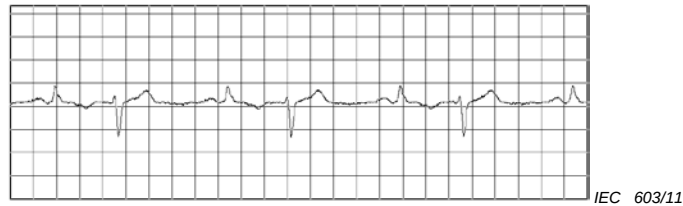
b) The following performance characteristics shall be disclosed.

- 1) **Respiration, leads-off sensing and active NOISE suppression.** For ME EQUIPMENT designed to intentionally apply a current to the PATIENT for the purpose of respiration sensing, leads-off sensing or active NOISE suppression, the MANUFACTURER shall disclose the waveforms (in the form of voltage, current, frequency, or other appropriate electrical parameters) which are applied to the PATIENT.
- 2) **Tall T-wave rejection capability.** Disclosure shall be made of the maximum T-wave amplitude that can be rejected, according to subclause 201.12.1.101.17.
- 3) **Heart rate averaging.** The type of averaging done to compute the minute heart rate and, if applicable, the updating rate of the display shall be disclosed.
- 4) **Heart rate meter accuracy and response to irregular rhythm.** Disclosure shall be made of the indicated heart rate, after a 20 s ME EQUIPMENT stabilization period, for the four types of alternating ECG complexes A1 to A4 described in Figure 201.101.

- 5) **Response time of heart rate meter to change in heart rate.** Disclosure shall be made of the maximum time, to the nearest second and including the update time of the ME EQUIPMENT, required for the heart rate meter to indicate a new heart rate for a step increase from 80/min to 120/min and a step decrease from 80/min to 40/min. The response time is measured from the time of the first QRS complex of the new rate to the time the heart rate meter first reads 37 % of the heart rate indication at 80/min plus (a) for the step increase, 63 % of the steady state indication at 120/min or greater, and (b) for the step decrease, 63 % of the steady state indication at 40/min or less.
- 6) **Time to alarm for tachycardia.** Disclosure shall be made of the time to alarm for the two ventricular tachycardia waveforms B1 and B2 shown in Figure 201.101, following a normal 80/min rate with the upper ALARM LIMIT set closest to 100/min and the lower ALARM LIMIT set closest to 60/min. Disclosure shall also be made of ME EQUIPMENT failure to alarm on either of these waveforms. In addition, the time to alarm shall be disclosed for these waveforms when their amplitudes are one-half and twice the indicated amplitudes.
- 7) **Pacemaker pulse rejection warning label.** The following or a similar warning shall be displayed in the instructions for use: "WARNING—PACEMAKER PATIENTS. Rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon heart rate meter ALARM SIGNALS. Keep pacemaker PATIENTS under close surveillance. See this manual for disclosure of the pacemaker pulse rejection capability of this instrument" (see 201.12.1.101.13).
- 8) **Visual and auditory ALARM SIGNAL disclosure.** The MANUFACTURER shall disclose the location where ALARM SIGNALS are displayed (i.e., central station, bedside, or both), color, size, and modulation (flashing), and the frequency or other descriptive characteristics of the sounds.
- 9) **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 function of the indicator of subclause 201.15.4.4.101 and the battery charging procedure shall also be disclosed.
- 10) **Auxiliary output.** Disclosure shall be made regarding proper connection of other devices to the auxiliary ECG signal output, if provided. The MANUFACTURER shall also disclose the bandwidth, GAIN and propagation delay time of all auxiliary outputs. MANUFACTURERS also shall disclose how internal pacemaker pulses are represented in the auxiliary output (their inclusion or absence, and whether enhanced pacemaker pulses are summed with the ECG signal).
- 11) **Pacemaker pulse rejection disabling.** If clinical OPERATOR accessible controls are provided that disable the pacemaker pulse rejection capability of the ME EQUIPMENT, the mode selection and whether the pacemaker pulse rejection (see 201.12.1.101.12/13) of the cardiograph is affected by this mode shall be disclosed.
- 12) **Sweep speeds.** The available time bases of PERMANENT and NON-PERMANENT DISPLAYS of the ME EQUIPMENT shall be disclosed.

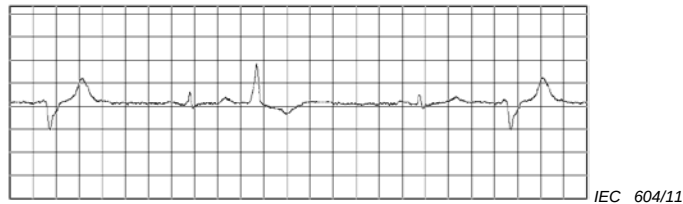
Grid intervals: 0.2 s, 0.5 mV

A1



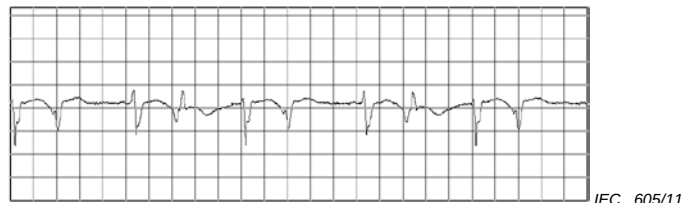
Ventricular bigeminy; the total duration for the double complex is 1,500 ms; the rate is 80/min if all QRS complexes are counted and 40/min if only the larger R waves or S waves are counted.

A2



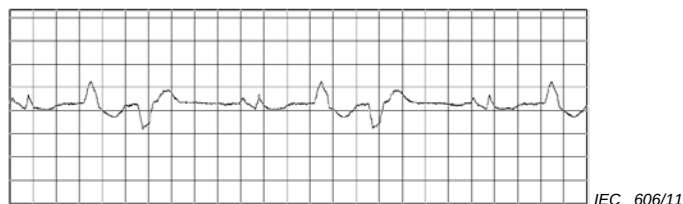
Slow alternating ventricular bigeminy; the rate is 60/min if all QRS complexes are counted and 30/min if only the large complexes are counted.

A3



Rapid alternating ventricular bigeminy; the rate is 120/min if all QRS complexes are counted.

A4



Bidirectional systoles; the rate is 90/min if all QRS complexes are counted and 45 1/min if only the large complexes are counted.

B1



Ventricular tachycardia; the amplitude is 1 mV peak-to-valley (p-v) and heart rate is 206/min.

B2



Ventricular tachycardia; the amplitude is 2 mV p-v and heart rate is 195/min.

NOTE These ECG test patterns (A1-B2) with defined amplitudes and time scale are available from <http://www.physionet.org>. GAIN or GAIN controls may be adjusted for each waveform.

Figure 201.101 – Alternating QRS complexes and ventricular tachycardia waveforms for testing pattern recognition capability according to 201.7.9.2.9.101 b) 4) and 6)

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 a), b), and c):

The APPLIED PART shall be a TYPE CF APPLIED PART.

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 DEFIBRILLATION-PROOF APPLIED PARTS

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 this particular standard.

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 PROTECTIVE 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.

Test ME EQUIPMENT having an INTERNAL ELECTRICAL POWER SOURCE, which is rechargeable from the SUPPLY MAINS 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 this particular standard.

- **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 this particular standard.

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.