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

AAMI
Advancing Safety in Healthcare Technology

American National Standard

ANSI/AAMI/IEC 60601-2-27:2011/(R)2016
(Revision of ANSI/AAMI EC13:2002/(R)2007)

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

Approved 24 June 2011 and reaffirmed 6 January 2017 by
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

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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
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IEC 60601-2-16:2008	ANSI/AAMI/IEC 60601-2-16:2008	Identical
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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
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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
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ISO 10993-10:2010	ANSI/AAMI/ISO 10993-10:2010	Identical
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ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002/(R)2008	Identical
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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
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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
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ISO 11140-1:2005	ANSI/AAMI/ISO 11140-1:2005/(R)2010	Identical
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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
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ISO 13408-6:2006	ANSI/AAMI/ISO 13408-6:2006	Identical
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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 w orldwide 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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8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International standard IEC 60601-2-27 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 r equirement 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 standard[1)] 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:

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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:

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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 LC D 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: ±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 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.

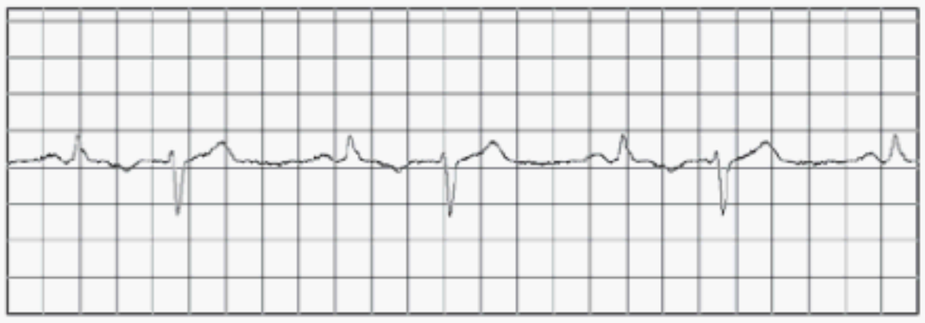
10) **Auxiliary output.** Disclosure shall be made regarding proper connection of other devices to the auxiliary ECG signal output, if provided. The MANUFACTURER shall also disclose the bandwidth, GAIN and propagation delay time of all auxiliary outputs. MANUFACTURERS also shall disclose how internal 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 cardiotach 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

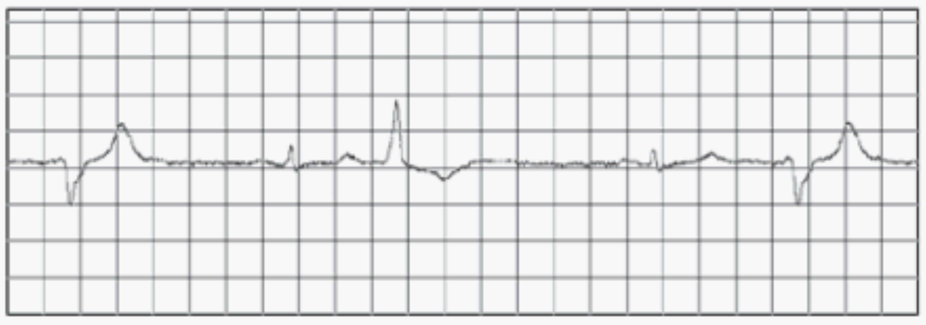
A1



IEC 603/11

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.

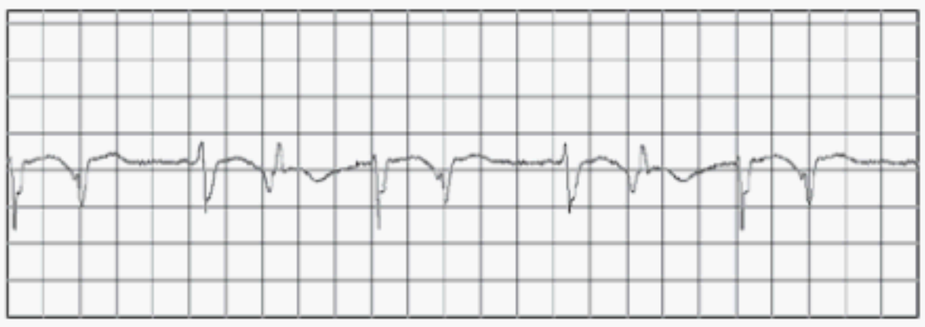
A2



IEC 604/11

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.

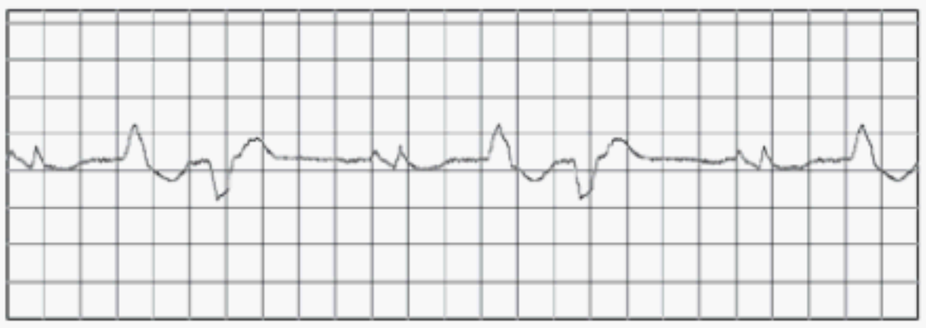
A3



IEC 605/11

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

A4



IEC 606/11

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

IEC 607/11

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

B2

IEC 608/11

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 ± 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 ± 50 %.

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

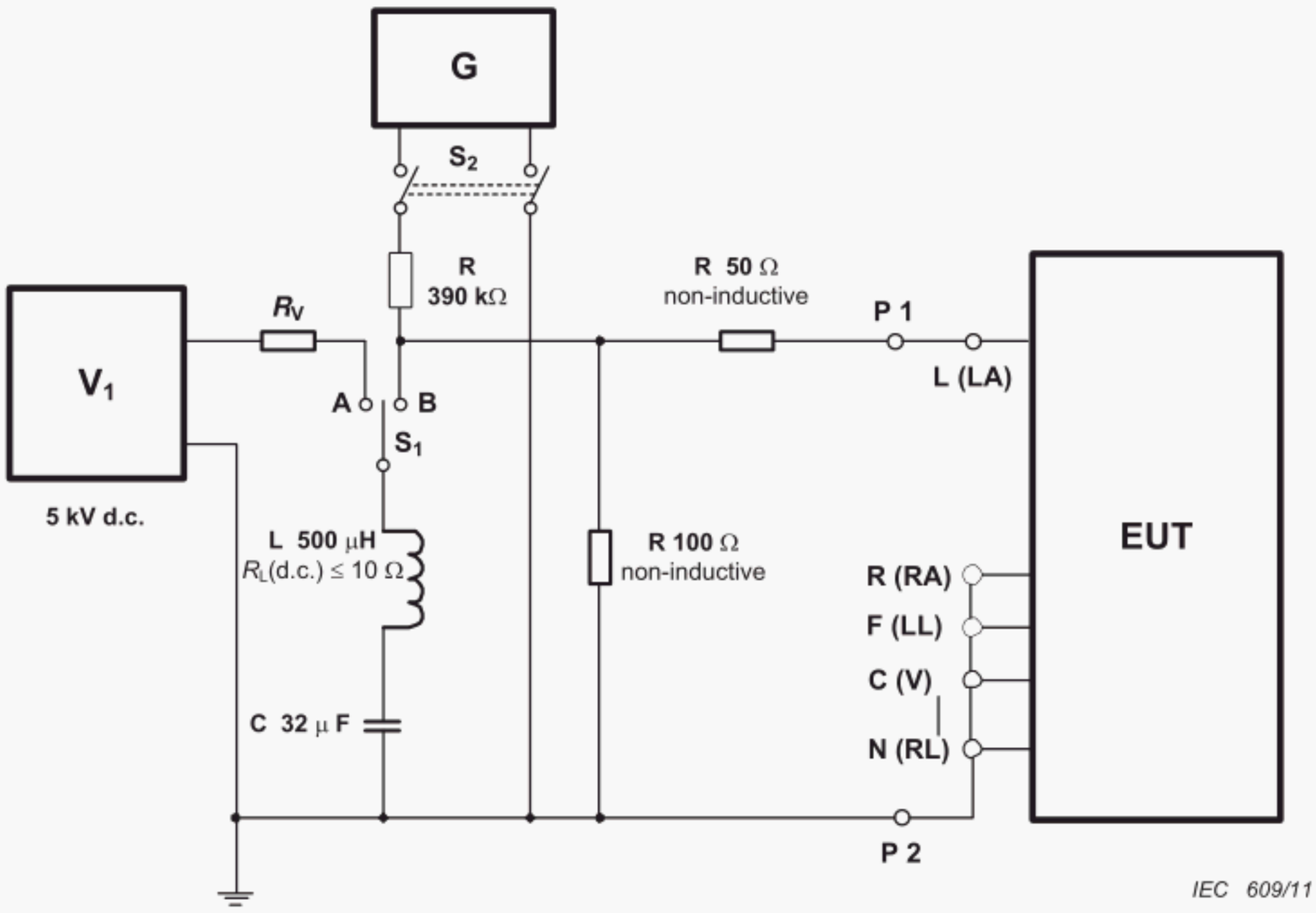
Immediately close S2. Within 5 s, verify that the recorded test signal is not less than 80 % of the output before application.

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
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

NOTE 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.

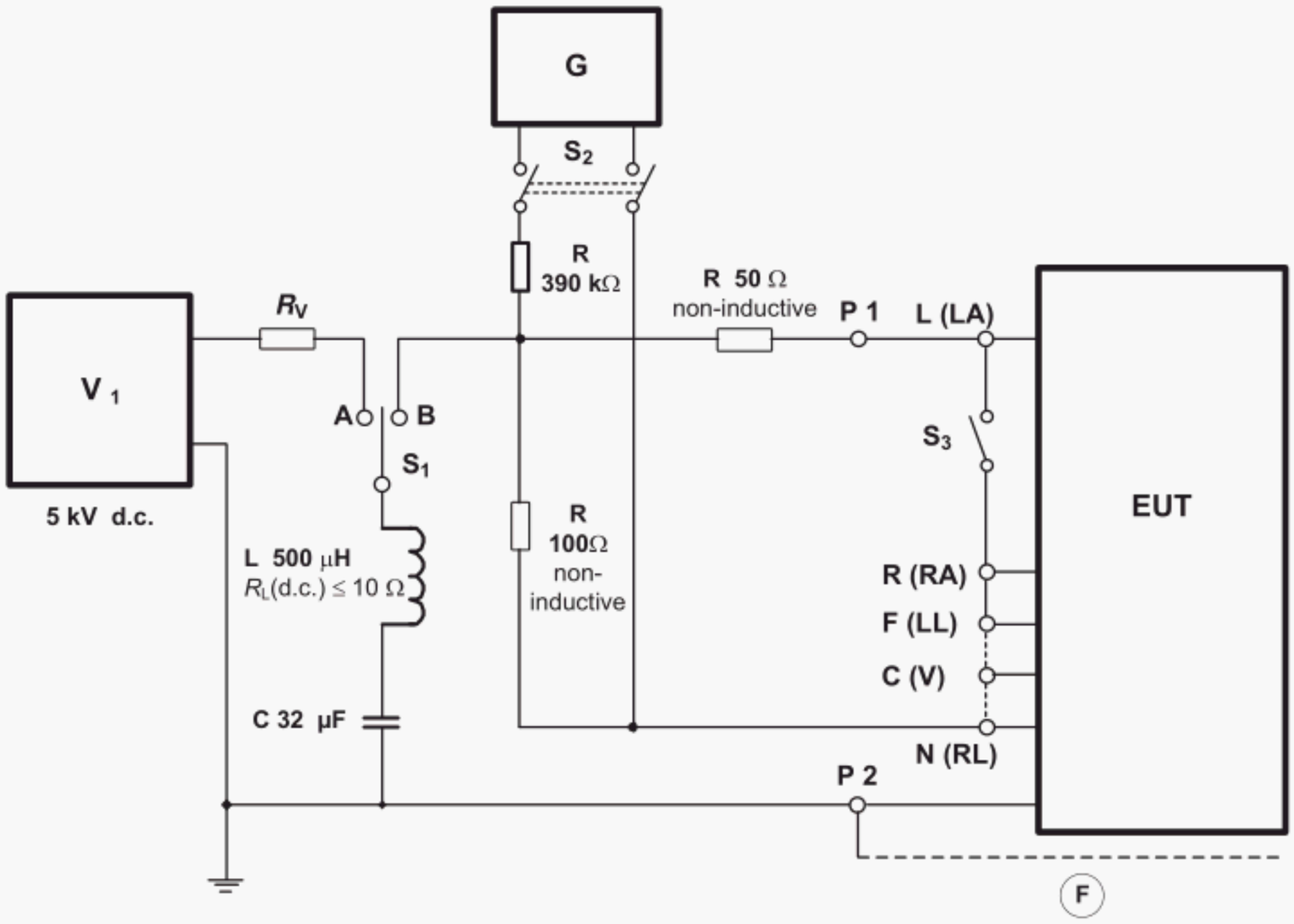


Components

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)



Components

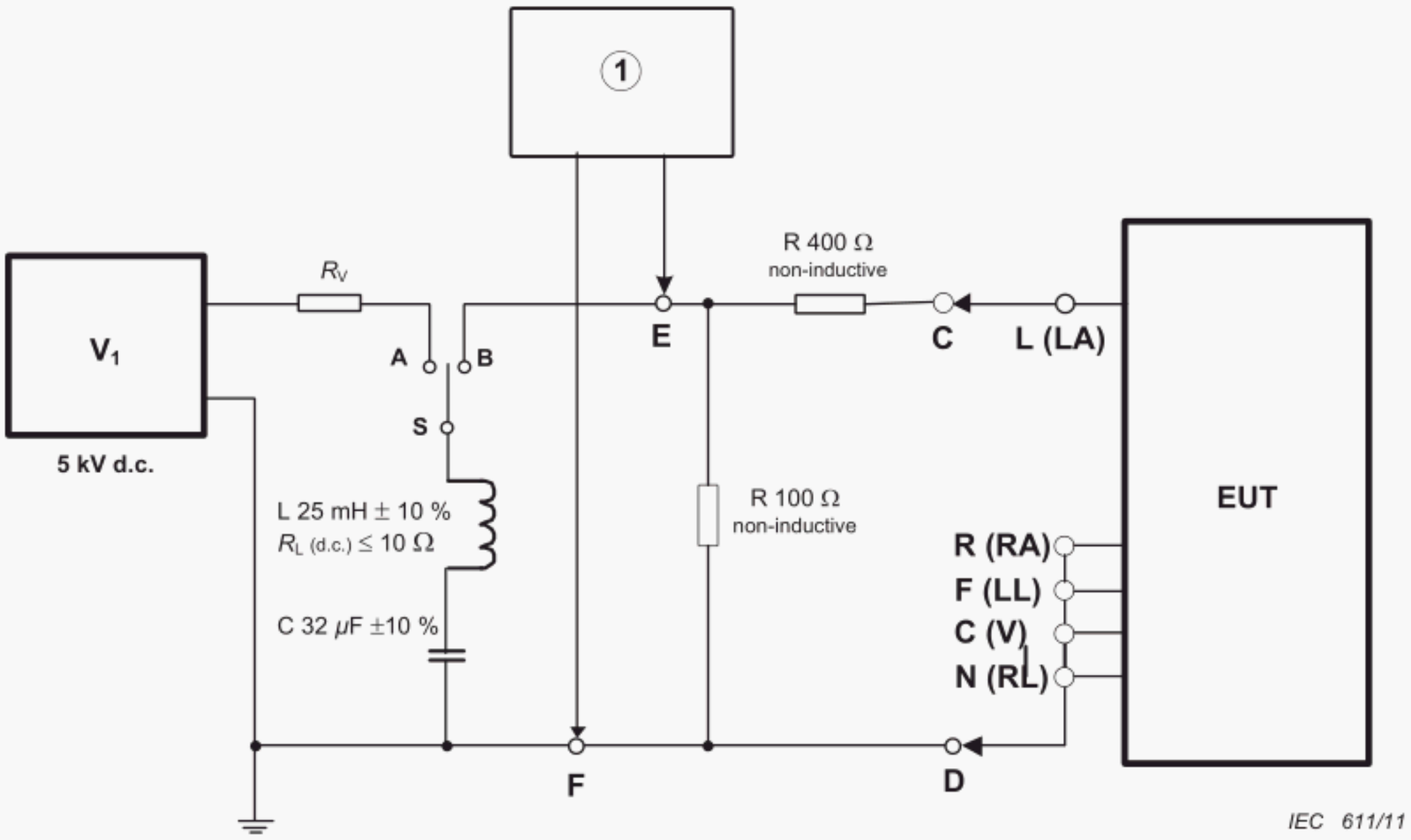
G	Sine wave generator 20 V peak-to-valley of 10 Hz
V_1	High voltage source 5 kV d.c.
Ⓕ	Foil, simulating capacitance for CLASS II EQUIPMENT
S_1	Switch; max. load 60 A, 5 kV
S_2	Switch connecting the signal source, 5 kV
S_3	Switch applying the signal source to LEAD WIRES
R_L	d.c. resistance of inductance L
R_V	Current limiting resistor
P1	Connecting point for EUT (includes PATIENT CABLES)
P2	Connecting point for FUNCTIONAL EARTH TERMINAL and/or metal foil in contact with ENCLOSURE

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

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

201.8.5.5.2 Energy reduction test

Replacement of Figure 11 by Figure 201.104:



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, except as follows:

201.11.6.5 * Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS

Addition:

PORTABLE/TRANSPORTABLE ME EQUIPMENT or parts of the ME EQUIPMENT separable while remaining functioning shall be constructed so that, in the event of spillage of liquids (accidental wetting) no HAZARDOUS SITUATION results from the ingress of liquids.

The ME EQUIPMENT shall meet the dielectric strength requirements specified in 8.8.3 of the general standard and shall comply with the requirements of this particular standard.

Compliance is checked by the following test:

Place the PORTABLE/TRANSPORTABLE ME EQUIPMENT or parts of the ME EQUIPMENT in the least favorable position of NORMAL USE. Subject the ME EQUIPMENT for 30 s to an artificial rainfall of 3 mm/min falling vertically from a height of 0.5 m above the top of the ME EQUIPMENT.

A test apparatus is shown in Figure 3 of IEC 60529.

An intercepting device may be used to determine the duration of the test.

Immediately after 30 s exposure, remove any visible moisture on the ENCLOSURE.

Immediately after the above test, verify (by inspection) that any water that entered the ME EQUIPMENT cannot adversely affect the BASIC SAFETY of the ME EQUIPMENT. Verify that the ME EQUIPMENT meets the relevant dielectric strength test (8.8.3 of the general standard) and does not result in a HAZARDOUS SITUATION.

After this test, verify that the ME EQUIPMENT complies with the requirements of this particular standard.

201.11.8 * Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT

Addition:

If the SUPPLY MAINS to the ME EQUIPMENT is interrupted for 30 s or less, no change of OPERATOR settings shall occur, including the mode of operation, and all stored PATIENT data shall remain available.

NOTE The ME EQUIPMENT does not have to be operating during the interruption of the SUPPLY MAINS.

Compliance is checked by observing the ME EQUIPMENT operating mode, OPERATOR settings, and stored data and interrupting the SUPPLY MAINS for a period of between 25 s and 30 s by disconnecting the POWER SUPPLY CORD.

If the SUPPLY MAINS is interrupted for more than 30 s, the subsequent operation shall be one of the following:

– reversion to the MANUFACTURER'S default settings,
– reversion to the previous RESPONSIBLE ORGANIZATION'S default settings or
– reversion to the last settings used.

NOTE Means may be provided to the OPERATOR to select one or more than one of the above options.

Compliance is checked by functional test.

If the ME EQUIPMENT contains an INTERNAL ELECTRICAL POWER SOURCE and the SUPPLY MAINS is interrupted, the ME EQUIPMENT shall continue normal operation by switching automatically to operating from its INTERNAL ELECTRICAL POWER SOURCE, and the mode of operation, all OPERATOR settings and stored data shall not be changed. Power-saving measures may be taken provided the ME EQUIPMENT continues to conform to this standard.

ME EQUIPMENT shall visually indicate when it is operating from its INTERNAL ELECTRICAL POWER SOURCE.

Compliance is checked by interrupting the SUPPLY MAINS and observing that OPERATOR settings and stored data are not changed, that normal operation continues, and that a visual indication is displayed that the ME EQUIPMENT is operating from its INTERNAL ELECTRICAL POWER SOURCE. The "on-off" switch needs to remain in the "on" position.

Addition:

201.11.8.101 * Protection against depletion of battery

ME EQUIPMENT powered from an INTERNAL ELECTRICAL POWER SOURCE shall not cause a HAZARDOUS SITUATION to the PATIENT when the state of discharge can no l onger maintain the NORMAL USE of the ME EQUIPMENT. The ME EQUIPMENT shall provide a TECHNICAL ALARM CONDITION to inform the clinical OPERATOR about the state of discharge and shall power down in a controlled manner as follows:

a) The ME EQUIPMENT shall provide a TECHNICAL ALARM CONDITION at least 5 min prior to the time that the ME EQUIPMENT can no longer function in accordance with the MANUFACTURER'S specification when powered from the INTERNAL ELECTRICAL POWER SOURCE.

   Compliance is checked by functional test.

b) When the state of discharge of any INTERNAL ELECTRICAL POWER SOURCE is such that the ME EQUIPMENT can no longer function in accordance with the MANUFACTURER's specification the ME EQUIPMENT shall power down in a manner which causes no HAZARDOUS SITUATION to the PATIENT.

   Compliance is checked by operating the ME EQUIPMENT from the INTERNAL ELECTRICAL POWER SOURCE and by functional test.

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 of ME EQUIPMENT

201.12.1.101.1 Accuracy of signal reproduction

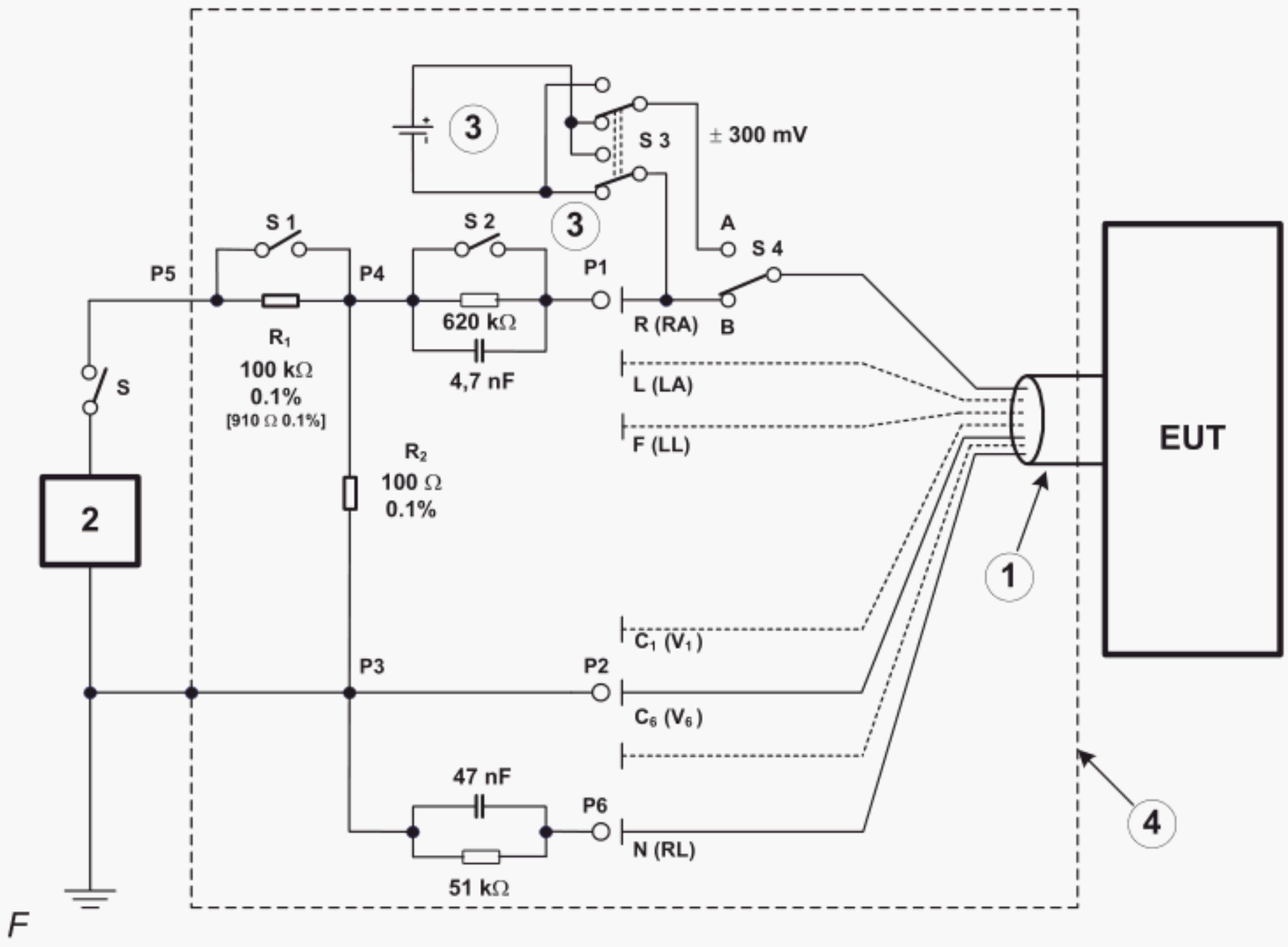
Input signals in the range of ±5 mV, varying at a rate up to 125 mV/s, shall be reproduced on the output with an error of ≤ ±20 % of the nominal value of the output or ±100 μV, whichever is greater.

Compliance is checked using the test circuit of Figure 201.105.

Open switch S1, close switches S and S2, and set S4 to position B. Connect the signal generator to apply a triangular wave of 2 Hz to any LEAD WIRE with all other LEAD WIRES connected to the N (RL) LEAD WIRE (P2) as defined in Table 201.103. Set the GAIN to 10 mm/mV and sweep speed to 25 mm/s. Adjust the signal generator to produce a peak-to-valley output on the NON-PERMANENT DISPLAY and on the PERMANENT DISPLAY (if provided), that is 100 % of the full scale peak-to-valley output. Decrease the output of the signal generator by factors of 2, 5 and 10. The displayed output shall be linear within ±20 % or ± 100 μV of the full scale output.

Repeat for each LEAD WIRE and NON-PERMANENT DISPLAYS and PERMANENT DISPLAYS, if provided until all combinations of LEAD WIRES and display devices have been tested as defined in Table 201.103.

Connect the signal generator to any LEAD WIRE with all other LEAD WIRES connected to the N (RL) LEAD WIRE (P2). Adjust the signal generator to apply a 2 mV peak-to-valley input 20 Hz sinusoidal signal. Set the GAIN to 10 mm/mV and sweep speed to 25 mm/s. Verify that the output signal is completely visible and the resulting peak-to-valley amplitude is between 16-24 mm.



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Components

① PATIENT CABLE

② Signal generator; output impedance < 1 kΩ and linearity ± 1 %

③ d.c. offset voltage source (300 mV)

④ Shield

$R_{1,2}$ Input voltage divider;

S_1 Switch, shorts signal source impedance

S_2 Switch, shorts unbalance caused by skin impedance

S_3 Switch, changes polarity of d.c. offset voltage source

S_4 Switch, connects/disconnects the d.c. offset voltage source

S Switch; connects/disconnects the signal generator

P1,2,6 LEAD WIRE connection points

P3,4 ECG input signal

P5 Signal generator; output signal

The shield around the entire test configuration minimizes induction from MAINS VOLTAGE.

The figure illustrates the general test circuit for:

- 201.12.1.101.1 (accuracy of signal reproduction);
- 201.12.1.101.2 (input dynamic range and differential offset voltage);
- 201.12.1.101.3 (input impedance);
- 201.12.1.101.4 (input NOISE);
- 201.12.1.101.5 (multichannel crosstalk);
- 201.12.1.101.6 (GAIN control and stability);
- 201.12.1.101.7 (sweep speed);
- 201.12.1.101.8 (frequency and impulse response);
- 201.12.1.101.9 (GAIN indicator)
- 201.12.1.101.11 (baseline reset);
- 201.12.1.101.14 (synchronizing pulse for cardioversion);
- 201.12.1.101.15 (heart rate range, accuracy and QRS detection range);

Figure 201.105 – General test circuit

201.12.1.101.2 * Input dynamic range and differential offset voltage

With a d.c. offset voltage in the range of ±300 mV and differential input signal voltages of ±5 mV that vary at rates up to 320 mV/s, when applied to any LEAD WIRE, the time-varying output signal amplitude shall not change by more than ±10 % over the specified range of d.c. offset.

Compliance is checked using the test circuit of Figure 201.105.

Open switch S1, close switches S and S2 and set S4 at position B. Apply a 16 Hz triangular or sinusoidal signal to any LEAD WIRE with all other LEAD WIRES connected to the N (RL) LEAD WIRE (P2) as defined in Table 201.103. Set the GAIN to 10 mm/mV and sweep speed to 25 mm/s. Adjust the signal generator so that the applied input signal produces an output amplitude of 80% of the full scale channel height. Record the amplitude of this output signal.

Set switch S4 to position A to apply a d.c. offset voltage of +300 mV. Measure the time-varying output signal amplitude. Verify that this amplitude is within ±10% of the previously recorded amplitude over the specified d.c. offset voltage range. Repeat this test for a d.c. offset voltage of –300 mV by changing the position of switch S3.

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

Repeat the test for each PERMANENT DISPLAY and NON-PERMANENT DISPLAY.

201.12.1.101.3 * Input impedance

The input impedance shall be at least 2.5 MΩ within a d.c. offset voltage range of ±300 mV. This requirement does not apply to inputs used for measurements other than ECG (i.e. respiration).

Compliance is checked using the test circuit of Figure 201.105.

Open switch S1, close switches S and S2 and set S4 to position B. Connect the sine wave signal generator to any tested LEAD (P1 and P2) with all other LEAD WIRES connected to the N (RL) LEAD WIRE (P6) as defined in Table 201.103. Set the GAIN to 10 mm/mV and sweep speed to 25 mm/s. Adjust the sine wave generator to produce a sinusoidal signal of 80 % of full-scale peak-to-valley channel height on any display at a frequency of 0.67 Hz. Record the displayed output amplitude for this GAIN at the PERMANENT or NON-PERMANENT DISPLAY being tested. Open S2 and set S4 to position A. Apply a d.c. offset voltage of +300 mV. The measured signal amplitude shall not decrease by more than 20 % on the output display. Repeat the test with a d.c. offset voltage of –300 mV. For d.c. offset voltages of +300 mV and –300 mV, repeat the test for a frequency of 40 Hz.

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

201.12.1.101.4 Input NOISE

The signal NOISE caused by the ECG amplifier and PATIENT CABLE shall not exceed 30 μV peak-to-valley referred to the input (RTI) for a period of at least 10 s. Any mains frequency notch filter, if provided, is to be turned on during this test.

Compliance is checked using the test circuit of Figure 201.107.

The PATIENT CABLE(S) specified by the MANUFACTURER shall be used when conducting the following test:

a) Insert in series with each LEAD WIRE of the PATIENT CABLE a 51 kΩ resistor in parallel with a 47 nF capacitor as shown in Figure 201.107; for this test all the switches S1 to Sn are open, and the signal generator G and the capacitor C1 are not connected.

b) With the ME EQUIPMENT adjusted for the highest GAIN setting, for the widest bandwidth setting, and for the switchable filters disabled, verify that the noise on the PERMANENT DISPLAY and NON-PERMANENT DISPLAY is no greater than 30 μV peak to valley referred to input for a period of at least 10 s, for each position of the LEAD SELECTOR.

c) Repeat this test nine more times. Verify that the 30 μV limit is not exceeded for at least nine of the 10 trials. The 10 trials must be conducted over a time period not to exceed 30 min. The PATIENT CABLE/LEAD WIRES must be motionless during these tests. The PATIENT CABLE must not be disconnected between trials.

201.12.1.101.5 Multichannel crosstalk

When an input signal limited in amplitude and rate as per 201.12.1.101.2 is applied to selected LEAD of the multi-channel ME EQUIPMENT, with all other LEAD WIRES connected to the N (RL) LEAD WIRE, the unwanted output in the unused LEADS shall not be greater than 5 % of the applied input signal.

For ME EQUIPMENT with standard and/or Frank LEADS, compliance is checked using the test circuit of Figure 201.105.

a) Open switch S1, close switches S and S2 and set S4 to position B. Connect LEAD WIRES F (LL), V1 (C1), and if provided, the Frank (E) to P1. Connect all other LEAD WIRES via P2 to the N (RL) LEAD WIRE (see Table 201.102) through a parallel combination of a 51 kΩ resistor and a 47 nF capacitor.

b) Set the GAIN to 10 mm/mV and sweep speed to 25 mm/s. Configure the ME EQUIPMENT to display LEADS I, II and III.

NOTE If the ME EQUIPMENT provides fewer than three simultaneous display channels then perform the test sequentially for each listed LEADS.

c) From the signal generator, apply 2.5 mV peak-to-valley 30 Hz triangular wave between P1and P2. Record the displayed output signals of LEAD I or Frank LEADS X and Y. Verify that the resulting value is less than 1.25 mm (5% of the 2.5 mV input signal).

d) Connect the F (LL) LEAD WIRE to P2 and the R (RA) LEAD WIRE to P1. All other LEAD WIRES remain connected as specified in a). Record the displayed output signals of LEAD I or Frank LEADS X and Y. Verify that the resulting value is less than 1.25 mm.

e) Connect the R (RA) LEAD WIRE to P2 and the L (LA) LEAD WIRE to P1. All other LEAD WIRES remain connected as specified in a). Record the displayed output signals of LEAD I or Frank LEADS X and Y. Verify that the resulting value is less than 1.25 mm.

f) Connect only the C1 (V1) LEAD WIRE to P1 and connect all other LEAD WIRES via P2 to the N (RL) LEAD WIRE through a parallel combination of a 51 kΩ resistor and a 47 nF capacitor. Record the displayed output signals of all LEADS. Verify that the resulting value (the displayed output signal of every LEAD except LEAD C1 (V1) is less than 1.25 mm.

g) Repeat step f) for the C2 (V2) through C6 (V6) LEAD WIRES connected in turn to P1 and with all other LEAD WIRES connected to P2. Record the displayed output signals of all LEADS. Verify that the resulting value (the displayed output signal of every LEAD except the LEAD associated with the LEAD WIRE currently connected to P1) is less than 1.25 mm.

h) Repeat step f) for all other LEAD WIRES.

i) For Frank leads, connect only the Frank A and F lead wires to P1 and all other lead wires to P2. The Frank LEADS X and Z must have output signals less than 1.25 mm (5% of the 2.5 mV input signal).

For ME EQUIPMENT with other LEADS, connections of an individual LEAD WIRE to P1 with all other LEAD WIRES connected to P2 must take into account the sharing of any specific LEAD WIRE with more than one LEAD before applying the 1.25 mm crosstalk limit.

201.12.1.101.6 GAIN control and stability

ME EQUIPMENT having PERMANENT and NON-PERMANENT DISPLAYS shall provide at least one fixed GAIN setting of (10 ± 1.0) mm/mV. In addition, continuously variable GAIN control may be provided, if this mode is clearly indicated on all provided displays.

Compliance is checked using the test circuit of Figure 201.105 and a ruler or calipers accurate to within 0.2 mm.

Open switch S1, close switches S, S2, and set S4 to position B. Connect R (RA) to P1, L (LA) to P2 and all other LEAD WIRES to P6. With the signal generator, apply a 1 mV 10 Hz peak-to-valley sinusoidal signal between the R (RA) and L (LA) LEAD WIRES.

For PERMANENT DISPLAYS, the GAIN setting of 10 mm/mV shall produce a displayed signal amplitude of (10 ± 1.0) mm. Adjust the input signal amplitude if the displayed signal is saturated or too small to measure, Measure the displayed signal amplitude for all implemented fixed GAIN settings. Verify that the displayed signal amplitude is within 10 % of the chosen GAIN setting.

For NON-PERMANENT DISPLAYS, repeat this test for all implemented fixed GAIN settings. Measure the displayed signal amplitude. Verify that the resulting value is within 10% of the chosen GAIN setting.

The GAIN change one minute after energizing the ME EQUIPMENT shall not exceed 0.66 % per minute. The total GAIN change shall not exceed ±10 % for periods of 1 min, 5 min, 30 min and 60 min

Compliance is checked using the test circuit of Figure 201.105 and a ruler or calipers accurate to within 0.2 mm.

After stabilizing at ambient temperature, energize the ME EQUIPMENT. Set the GAIN to 10 mm/mV and sweep speed to 25 mm/s. Apply a 1 mV peak-to-valley 10 Hz signal. Measure the displayed output amplitude after 1 min, 5 min, 30 min and 60 min. Verify that the displayed output amplitude varies less than ±1 mm between any measurements or 0.66 % per minute. Other fix GAIN settings may be used to determine the GAIN stability of NON-PERMANENT DISPLAYS. In this case verify that the displayed output amplitude varies less than ±1 mm multiplied by factor "selected fix GAIN divided by 10 mm/mV" between any measurements or 0.66 % per minute.

201.12.1.101.7 Sweep speed

ME EQUIPMENT with PERMANENT DISPLAYS shall provide at least one sweep speed of 25 mm/s ±10 %. ME EQUIPMENT with NON-PERMANENT DISPLAYS shall provide at least one sweep speed that is labeled 25 mm/s and has a waveform aspect ratio as specified in 201.12.1.101.16 at a GAIN setting of 10 mm/mV.

Other sweep speeds may be provided. The MANUFACTURER shall disclose all available sweep speeds (see 201.7.9.2.9.101 b) 12)). The sweep speed accuracy for any settings shall not vary by more than ±10 % over the complete horizontal ECG-channel width.

Compliance is checked using the test circuit of Figure 201.105 and a ruler or calipers accurate to within 0.2 mm.

Connect a signal generator between the R (RA) LEAD WIRE and all other LEAD WIRES connected to the N (RL) LEAD WIRE. Set the GAIN to 10 mm/mV and the sweep speed to 25 mm/s. Apply a 0.5 mV peak-to-valley triangular or sinusoidal signal of 25 Hz ±1 %.

For PERMANENT DISPLAYS, generate a printout that contains at least 6 s of the applied signal at this sweep speed. Ignore the signal from the first 1 s interval and measure the distance between any 25 successive peaks. This distance must be (25 ± 2.5) mm. Repeat the measurements at least three times along different parts of the printout and verify that these measurements remain within (25 ± 2.5) mm.

For NON-PERMANENT DISPLAYS, measure the width (in mm) of the waveform portion of the display at the height of the vertical midpoint of this signal. Using either a time-exposure photograph of the display or an image captured from the display, count the number of upper or lower peaks within this image/photograph. Divide the measured width of the waveform channel (in mm) by the number of peaks (of this 25 Hz signal). This resulting value must be (1 ± 0.1) mm.

Other available sweep speeds are checked by visual inspection.

201.12.1.101.8 * Frequency and impulse response

The frequency and impulse response of ME EQUIPMENT shall comply with the following requirements:

a) Frequency response

ME EQUIPMENT shall meet the requirement for a frequency response (bandwidth) of at least 0.67 Hz to 40 Hz when tested with the input signals from methods A and B. For Method A, the output at 0.67 Hz and 40 Hz shall be within 71 % to 110 % of the output obtained with a 5 Hz sine wave input signal. For Method B, the output response obtained with the waveform of Figure 201.106 with a 20 ms base width shall be within 75 % to 100 % of the output obtained with a base width of 200 ms.

Compliance is checked using the test circuit of Figure 201.105 and application of test methods A and B. Ensure that the line frequency notch filter, if provided, is turned off for this test.

If the ME EQUIPMENT provides additional selectable ECG bandwidths or filter settings, then test each setting appropriately as specified by the MANUFACTURER.

Method A: Open switch S1, close switches S and S2 and set S4 to position B. Set the GAIN to 10 mm/mV and sweep speed to 25 mm/s. Use the signal generator to apply a 5 Hz, 1 mV peak-to-valley sine wave signal to the R (RA) LEAD WIRE with all other LEAD WIRES connected to the N (RL) LEAD WIRE. Record the displayed output amplitude in LEAD II for that GAIN on the PERMANENT or NON-PERMANENT DISPLAY being tested. Verify that at 0.67 Hz and 40 Hz the output signal amplitude remains within the range of 71 % to 110 % compared to the amplitude of 5 Hz.

Method B: Close switches S and S2 and set S4 to position B. Set the GAIN to 10 mm/mV and sweep speed to 25 mm/s. Use the signal generator to apply the waveform of Figure 201.106 with a base width of (200 ± 20) ms to the F (LL) LEAD WIRE with all other LEAD WIRES connected to the N (RL) LEAD WIRE. Adjust the input signal to produce an output amplitude equivalent to (20 ± 0.5) mm in LEAD II. Then, without changing the input amplitude, change the base width to (20 ± 1) ms. The repetition rate, selected to obtain the most irregular pattern of amplitudes of successive output peaks, may be 1 Hz or lower.

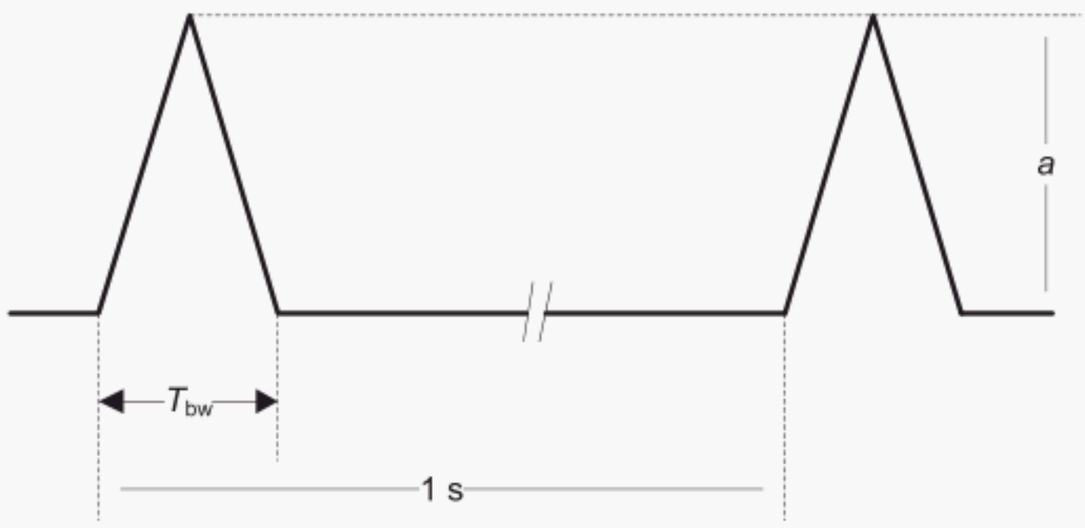
For each of 10 consecutive cycles, locate the point of maximum amplitude (M). Locate the point (P) that lies midway between the peaks of consecutive cycles. Each peak amplitude is computed as the difference between amplitude M and the baseline value P preceding M. This amplitude must be within the range 75 % to 100 % (15 mm to 20 mm nominal) of the peak amplitude recorded for the 200 ms triangular wave input signal.

b) Impulse response

The extended low-frequency response shall not produce a displacement greater than 0.1 mV RTI, nor a slope exceeding 0.3 mV/s immediately following the end of the impulse on the output when an input impulse of 0.3 mV•s (3 mV for 100 ms) is applied.

Compliance is checked using the test circuit of Figure 201.105 and a ruler or calipers accurate to within 0.2 mm.

Open switch S1, close switches S and S2 and set S4 to position B. Set the GAIN to 10 mm/mV and sweep speed to 25 mm/s. Apply an input impulse of 3 mV amplitude and 100 ms duration to the R (RA) LEAD WIRE with all other LEAD WIRES connected to the N (RL) LEAD WIRE. Verify that the output baseline following the impulse is displaced no more than 0.1 mV from the baseline preceding the impulse and that the slope of the response does not exceed 0.3 mV/s following the end of the pulse. If the applied impulse triggers the pacemaker detector a modified impulse with a lower amplitude and longer duration but still having a 0.3 mVs area may be used.



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Key

T_{bw} 20 ms or 200 ms

Figure 201.106 – High frequency response
(see 201.12.1.101.8 a)

201.12.1.101.9 GAIN INDICATOR

A GAIN INDICATOR shall be provided that indicates the amplitude of an input voltage of 1 mV for each GAIN setting on PERMANENT and NON-PERMANENT DISPLAYS. The amplitude variation in display output shall be within ±10 % when applying a (1.00 ± 0.01) mV input signal at the

appropriate LEAD. It shall be available for all LEADS. The GAIN setting may be pr ovided alternatively as a numerical value expressed in mm/mV. ME EQUIPMENT providing only one fixed GAIN is exempt from the requirement to provide a GAIN INDICATOR.

NOTE Examples of a GAIN INDICATOR are a vertical bar or a horizontal line (gridline, dotted line) representing the amplitude a 1 mV input signal.

If the GAIN INDICATOR of 1 mV exceeds the channel height the GAIN INDICATOR may be rescaled. In this case the amplitude of the GAIN INDICATOR shall be indicated.

Compliance is checked using the test circuit of Figure 201.105, the test signal of Figure 201.106 and a ruler or calipers accurate to within 0.2 mm.

Open switch S1, close switches S and S2 and set S4 to position B. Set the GAIN to 10 mm/mV and sweep speed to 25 mm/s. With the signal generator apply a (1.00 ± 0.01) mV peak-to-valley triangular or sinusoidal signal of 25 Hz to the R (RA) LEAD WIRE with all other LEAD WIRES connected to the N (RL) LEAD WIRE. Record the amplitude of the GAIN INDICATOR and verify that it is within 10 % of the displayed output signal. Repeat the test for all LEADS and the minimum and maximum GAIN setting.

201.12.1.101.10 * Common mode rejection

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

Compliance is checked using the test circuit of Figure 201.107 and a ruler or calipers accurate to within 0.2 mm. The test has to be performed with main frequencies of 50 Hz and 60 Hz.

a) *Adjust C_t to produce 10 V r.m.s. at mains frequency at point B, while no PATIENT CABLE is attached (S0 open). The common mode voltage applied to the ME EQUIPMENT is then 10 V rms. Ensure that the line frequency notch filter (if provided) is turned off for this test, even if this requires special software or a special method of accessing the control over that filter.*

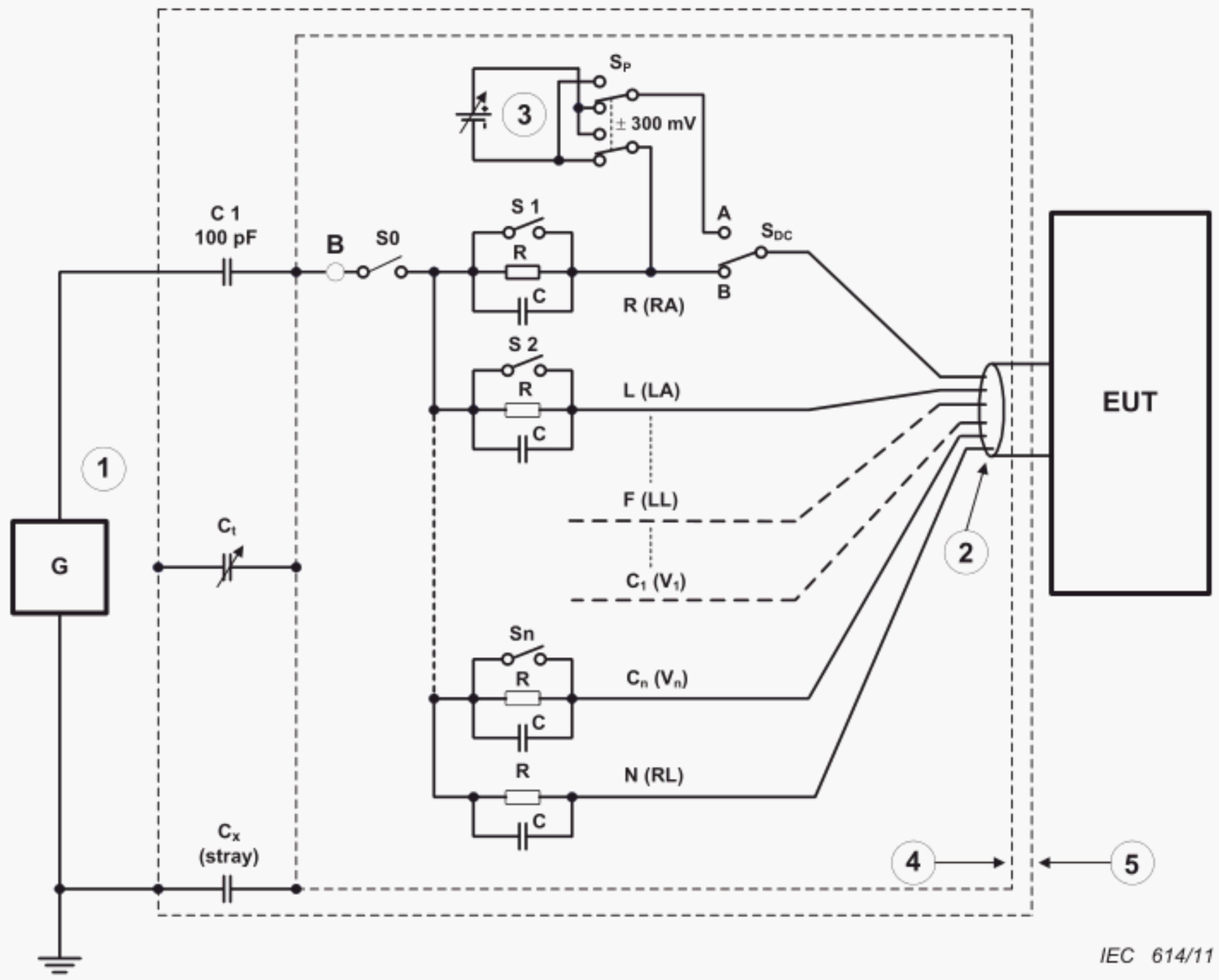
b) *Close switches S0 and S2 through S_n, open S1, and set S_{DC} to position B. Set the GAIN to 10 mm/mV and the sweep speed to 25 mm/s. Measure the output amplitude for not less than 15 s period at that GAIN setting. Then open S2 and close all other switches. Repeat the amplitude measurement. Continue until the measurement has been made with all LEAD WIRES.*

c) *Repeat the test with a +300 mV d.c. and –300 mV d.c. offset voltage in series with the imbalance impedance, by setting S_{DC} to position A and testing with switch S_P in each of its two positions.*

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

In Figure 201.107 C_1 and C_t simulate the PATIENT'S capacitance to ground. The inner shield reduces the pickup of unwanted extraneous signals. Since the capacitance C_x between the inner and external shields influences both the source capacitance and the common mode voltage, this capacitance is increased by a trimmer capacitor to 100 pF, equal to the generator capacitor C_1. The generator output is increased to 20 V_{rms}, thus providing 10 V_{rms} at the common mode

point B with a source impedance equivalent to 200 pF when the PATIENT CABLE is not connected to the test circuit. The shield of the PATIENT CABLE must not be connected.



Components

① Signal generator 20 V_{rms} mains frequency

② PATIENT CABLE

③ DC offset source, impedance ≤ 1 kΩ

④ Inner shield

⑤ Outer shield

B Common mode point

S1-Sn Switches; invoke unbalance circuit consisting of C and R

C 47 nF

R 51 kΩ

Figure 201.107 – Test circuit for COMMON MODE REJECTION
(see 201.12.1.101.10)

201.12.1.101.11 Baseline reset

Means shall be provided for restoring the ME EQUIPMENT to its normal operating condition within 3 s after applying a 1 V peak-to-valley 50/60 Hz overload voltage for at least 1 s.

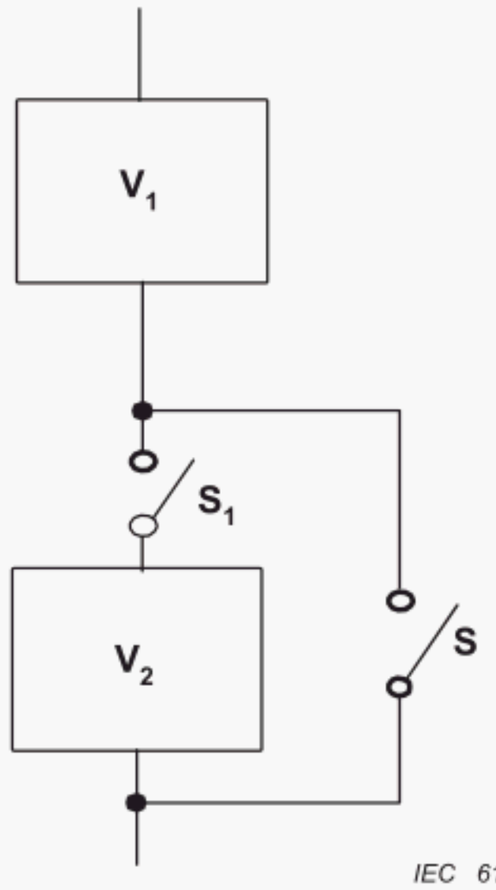
Compliance is checked by the following test:

a) Connect the ME EQUIPMENT to the test circuit of Figure 201.105 with switches S, S1 and S2 closed, S4 in position B and the generator circuit of Figure 201.108 with switch S closed and

S1 open; adjust the sinusoidal generator V1 to produce a 10 Hz, 1 mV peak-to-valley signal between the selected LEAD WIRES;

b) *Select any available LEAD and corresponding LEAD WIRE combination, and by means of opening the switch S and closing the switch S1 in Figure 201.108, apply a 50/60 Hz, 1 V peak-to-valley overload voltage for at least 1 s;*

c) *Close switch S and open switch S1 in Figure 201.108 and verify that the 10 Hz signal is clearly visible 3 s after closure of the switch across V2 and remains visible.*



Components

V_1 Signal generator 1 mV peak-to-valley, 10 Hz sine wave
V_2 Signal generator 1 V peak-to-valley, 50Hz/60 Hz mains frequency
S Switch enabling/disabling 50 Hz/60 Hz mains frequency

Figure 201.108 – Baseline reset
(see 201.12.1.101.11)

201.12.1.101.12 * Pacemaker pulse display capability

ME EQUIPMENT shall be capable of displaying the ECG signal in the presence of pacemaker pulses with amplitudes of ±2 mV to ±700 mV and durations of 0.5 ms to 2.0 ms. An indication of the pacemaker pulse shall be visible on the display with an amplitude of no less than 0.2 mV referred to input (RTI). Alternatively, the position of pacemaker pulses may be indicated by artificially inserted pacemaker pulse flags. If the display capability of pacemaker pulses is affected by patient modes such as neonatal mode or filter settings the positions of these inserted pacemaker flags in these modes shall be verified.

Compliance is checked using the test circuit of Figure 201.114 and the waveform of Figure 201.109.

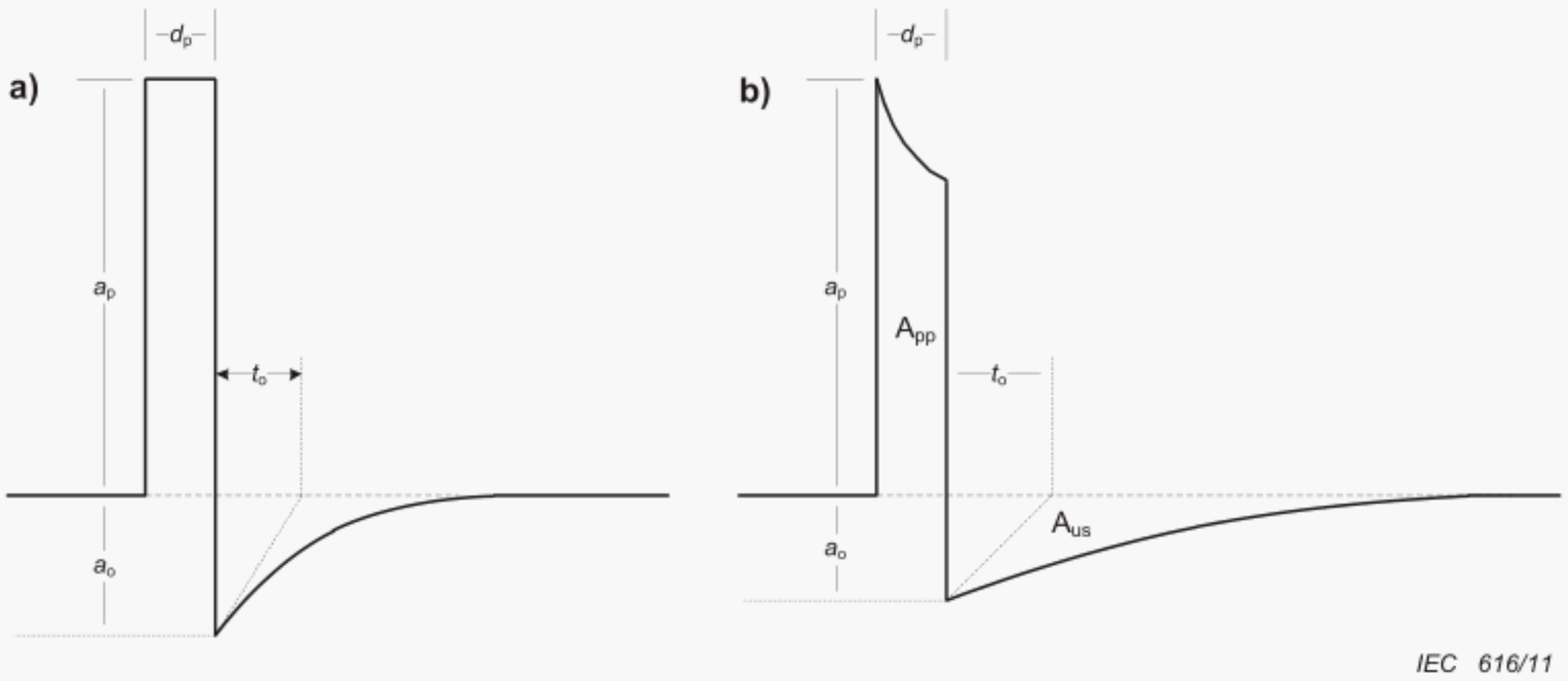
Connect the R (RA) LEAD WIRE to P1 and all other LEAD WIRES and N (RL) LEAD WIRE to P2. Set the GAIN to 10 mm/mV and sweep speed to 25 mm/s. Apply with the pacemaker pulse generator (2) the waveform of Figure 201.109. The QRS simulator (1) is switched off for this test. Adjust amplitude a_p of the pacemaker pulse to (700 ± 70) mV. Adjust the pacemaker pulse frequency to 1.5 Hz. Adjust the pulse width d_p to (2 ± 0.2) ms. Verify that the indication of the pacemaker

pulse is visible on the display with an amplitude of at least 0.2 mV RTI or that position of pacemaker pulses may be indicated by inserted pace pulse flags.

Adjust the pulse width d_p to (0.5 ± 0.05) ms and repeat the test.

Change the amplitude a_p of the pacemaker pulse to (2 ± 0.02) mV and repeat all the above tests.

Repeat the test for all other LEAD WIRES and corresponding LEAD SELECTOR positions as defined in Table 201.103. Repeat the test for all modes that may affect the capability of displaying pacemaker pulses or artificially inserted pacemaker flags.



Key

A	Pacemaker pulse without overshoot
B	Pacemaker pulse with overshoot (a.c. coupled, area $A_{pp} = A_{us}$)
a_p	Amplitude (variable from 2 mV to 700 mV)
a_o	Overshoot (see text)
d_p	Pulse width (variable from 0.1 ms to 2.0 ms)
t_o	Overshoot time constant (4 ms to 100 ms)

Rise and fall times of the pacemaker pulse shall not exceed 10 % of d_p or 100 μs.

Figure 201.109 – Pacemaker pulse
(see 201.12.1.101.12)

201.12.1.101.13 Rejection of pacemaker pulses

Disclosure (see subclause 201.7.9.2.9.101 b) 7)) shall be made of whether the ME EQUIPMENT rejects all pacemaker pulses having amplitudes (a_p) from ±2 mV to ±700 mV and pulse widths from 0.1 ms to 2.0 ms. If the ME EQUIPMENT cannot effectively reject pacemaker pulses in this range, disclosure shall be m ade of the range of pulse amplitudes and widths that the ME EQUIPMENT can reject. The ME EQUIPMENT'S pacemaker pulse rejection capability shall be disclosed for

a) pacemaker pulses alone of the form shown in Figure 201.109;

b) pacemaker pulses with a normally paced QRS and T-wave (Figure 201.111); and

c) pacemaker pulses with an ineffectively paced QRS pattern (Figure 201.112).

Disclosure of rejection capability also shall be made for (a), (b), and (c) above when an atrial pacemaker pulse with identical amplitude and duration precedes a ventricular pacemaker pulse by 150 ms to 250 ms.

If means are provided to disable the pacemaker pulse rejection capability of the ME EQUIPMENT, a visible indication shall be displayed to inform the clinical OPERATOR that the pacemaker pulse rejection is disabled.

The applied test signals of Figure 201.109 shall be as follows:

– method A - test signal a) for pacemaker pulses without overshoot: the overshoot (a_o) shall be less than 5 % of pacemaker amplitude (0.05 a_p in Figure 201.109), and the settling time of the overshoot must be less than 5 μs; the rise and fall times shall be 10 % of the pulse width, but not greater than 100 μs. The rising edge of the pacemaker pulse shall occur between 10 ms and 40 ms before the onset of the QRS complex as outlined in Figure 201.111;
– method B - test signal b) for pacemaker pulses with overshoot: same signal as specified in test signal of method A but the overshoot (a_0) shall have recharge time constants (t_0) between 4 ms and 100 ms.

Compliance is checked by using the test circuit of Figure 201.114 and the signal generator waveform of Figures 201.109, 201.111, 201.112, and 201.113.

In Figure 201.114 connect LEAD WIRE R (RA) to position P1 and all other LEAD WIRES to position P2.

If the MANUFACTURER'S specifications for the ME EQUIPMENT encompass anything other than this particular standard's full ranges (amplitude = ±2 mV to ±700 mV, duration = 0.1 ms to 2 ms, and overshoot = 4 ms to 100 ms, as defined by method A and method B), perform the following tests using the amplitudes, durations and overshoots specified by the MANUFACTURER.

a) Apply the waveform of Figures 201.109/201.111 to the ME EQUIPMENT input, with QRS amplitude (a) in Figure 201.113 set at 1 mV, QRS duration (d) at 100 ms, and from Figure 201.110, T-wave amplitude (a_T) at 0.2 mV, T-wave duration (d_T) at 180 ms, QT interval (d_{QT}) at 350 ms, and R-R interval at 1 s. Set the amplitude of the pacemaker pulse to +2 mV. Adjust the pulse width (d_P) to 2 ms.

b) The GAIN control, if provided, may be adjusted only at this point in the test sequence.

c) Verify that the indicated heart rate agrees with the values disclosed by the MANUFACTURER.

d) Remove the QRS and T-wave signal and verify that the indicated heart rates agree with those disclosed by the MANUFACTURER.

e) Repeat the above steps a), c) and d) for pacemaker pulse amplitudes (a_P) of –2 mV, ±100 mV, ±300 mV, ±500 mV, ±700 mV.

f) Apply the test waveform of Figure 201.112 to the ME EQUIPMENT input with the same parameters as in step a) except that the heart rate is set to 30/min and the pacing rate to 80/min (during this test, the heart rate must be such that the pacemaker pulse to drifts asynchronously through the ECG waveform).

g) Apply a pulse with amplitude and duration identical to the ventricular pacemaker pulse, but preceding the latter by 150 ms, and repeat steps (a) through (f) with both pacemaker pulses present.

h) Repeat step (g) using an interval of 250 ms instead of 150 ms between pacemaker pulses.

i) Verify that the indicated heart rate agrees with the values disclosed by the MANUFACTURER.

j) Repeat steps (f), (g) and h) for a_P of –2 mV, ±100 mV, ±300 mV, ±500 mV, and ±700 mV.

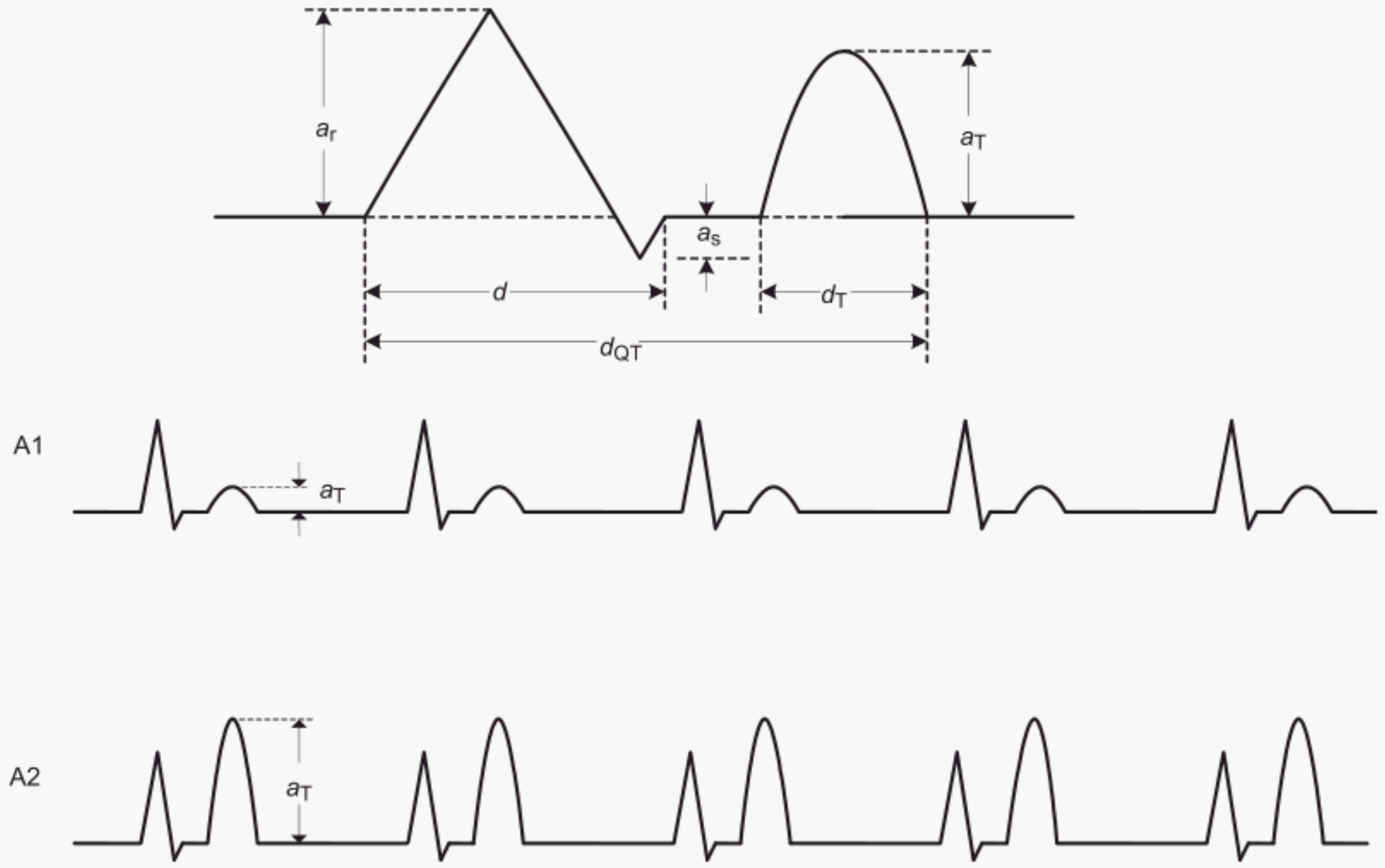
k) Repeat the entire test sequence for pacemaker pulses having the parameters of the described test signal (b). The amplitude of the overshoot (a_0) may be set based on either method A (= 0.025 a_P to 0.25 a_P, but not to exceed 2 mV, independent of time constant), method B (= $a_P d_P / t_0$), or both.

NOTE For method B, capacitive coupling may cause the main pulse to sag by an amount equal to the overshoot's amplitude. Also, with A-V sequential pacemaker pulses, the overshoot of the ventricular pulse must include any residual left over from unsettled overshoot of the atrial pulse.

l) Repeat tests a) through k) for a pulse width (d_P) of 0.1 ms.

m) If the ME EQUIPMENT behaves differently for the above tests while in different PATIENT modes (particularly neonate mode), repeat this test in all PATIENT modes.

If means are provided that disable the pacemaker pulse rejection capability, activate these means and verify display of a visual indication that pacemaker pulse rejection is disabled.



IEC 617/11

Key

a_r	Amplitude of QR segment
a_s	Amplitude of RS undershoot
a_T	Amplitude of T-wave
d	Duration of QRS
d_T	Duration of T-wave
d_{QT}	Duration of QT segment

Figure 201.110 – Test waveforms for T-wave rejection
(see 201.7.9.2.9.101 b)2), 201.12.1.101.13, 201.12.1.101.17)

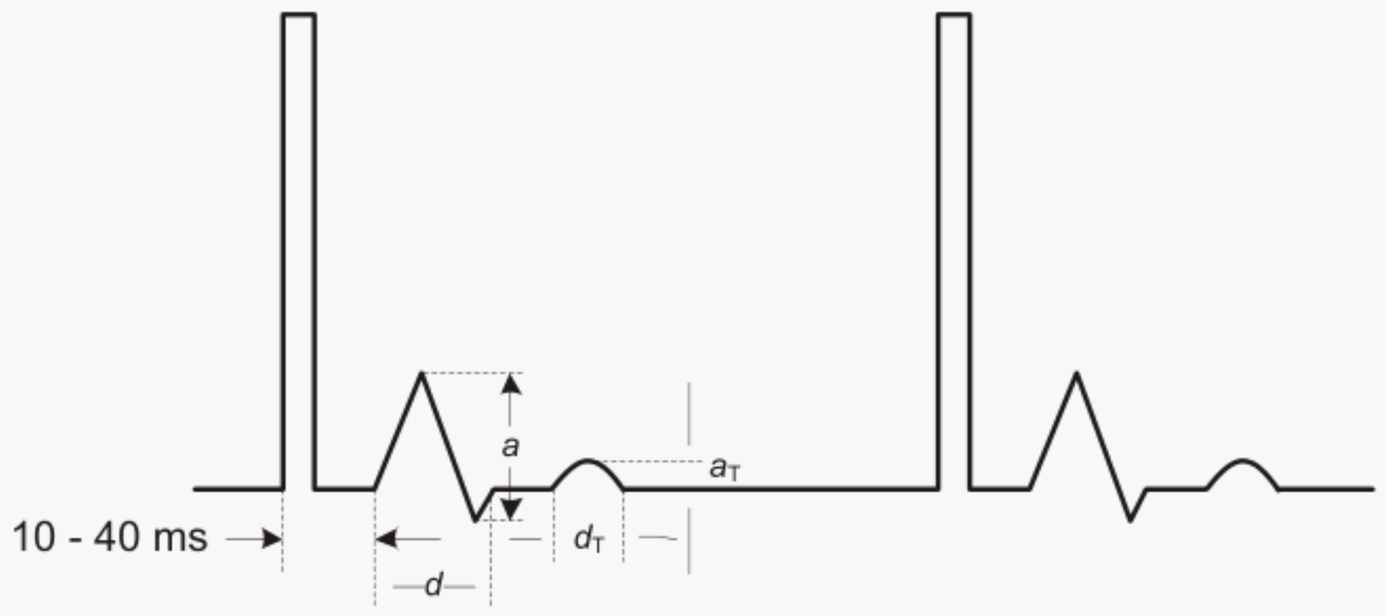


Figure 201.111 – Normal paced rhythm
(see 201.12.1.101.13 and Figure 201.113

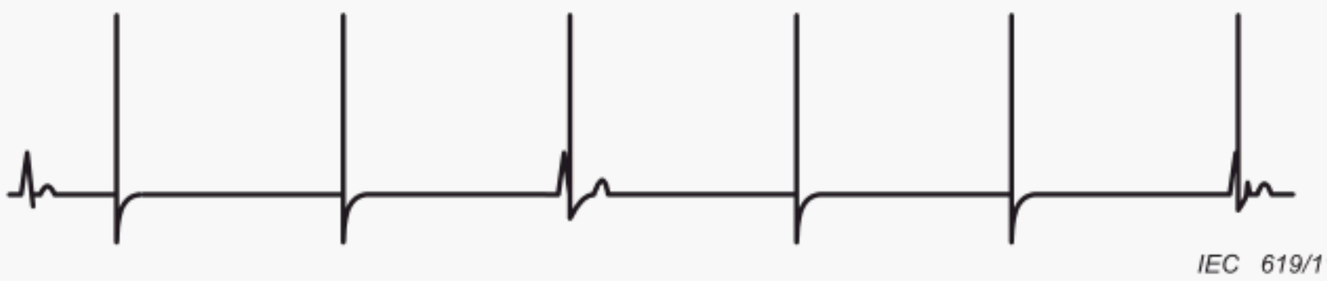


Figure 201.112 – Ineffective pacing (heart rate at 30/min, pacemaker pulse at 80/min)
(see 201.12.1.101.13)

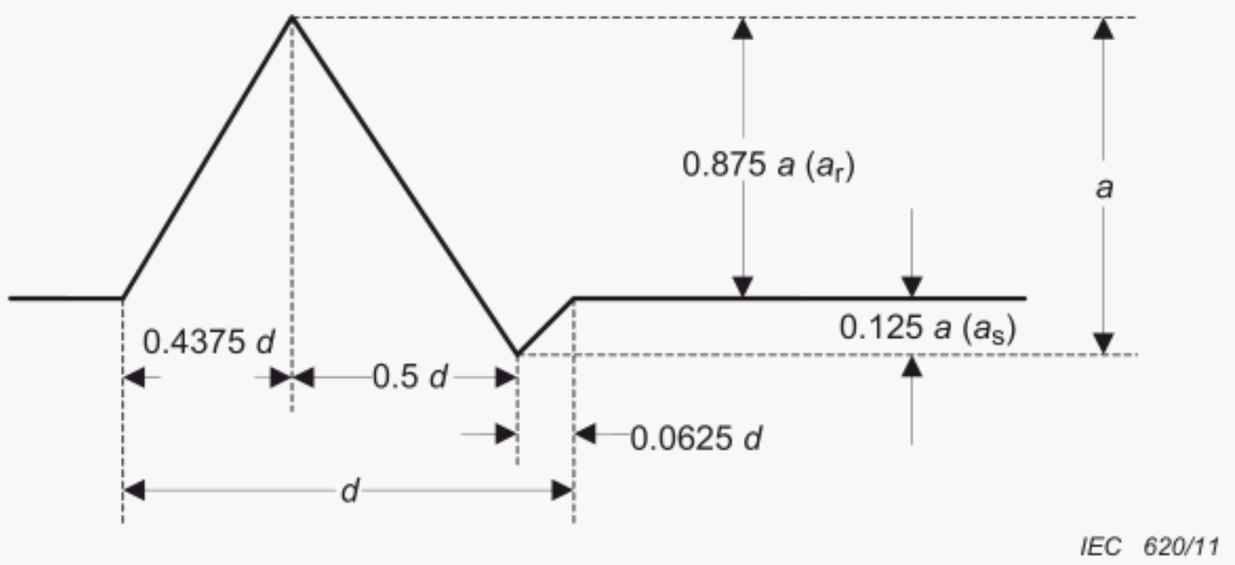
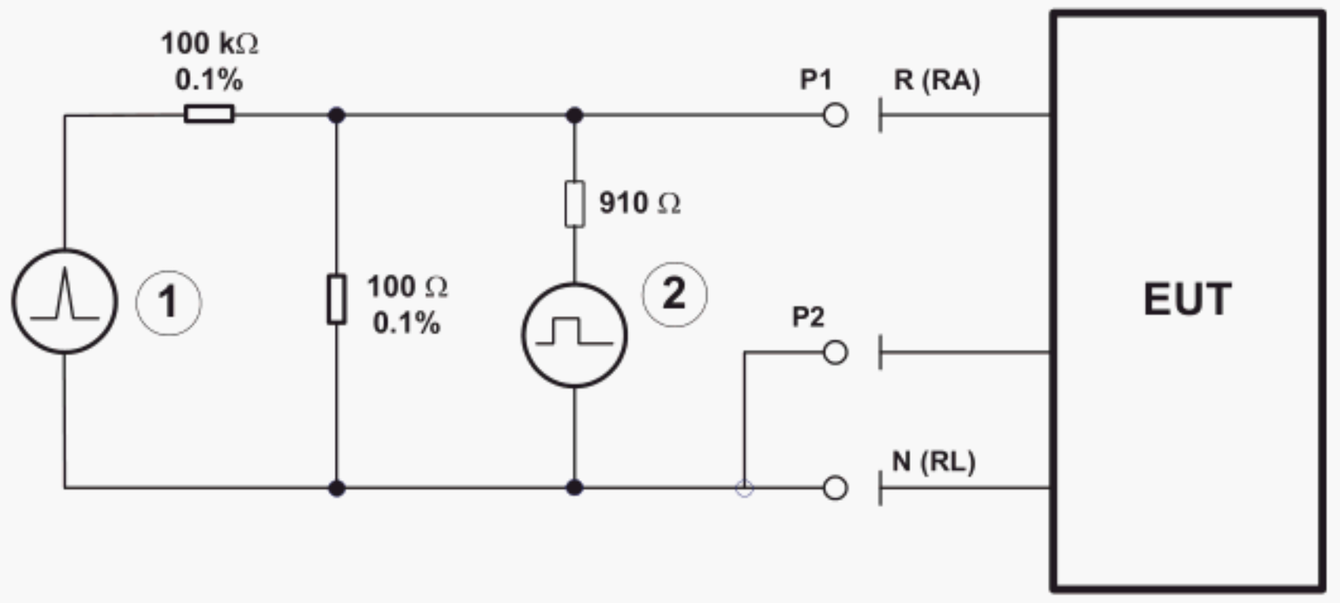


Figure 201.113 – Simulated QRS complex
(see 201.12.1.101.13, 201.12.1.101.14 and 201.12.1.101.15)



IEC 621/11

Components

① QRS simulator; output impedance < 1 kΩ and linearity ± 1 %; 1 V peak-to-valley, 40 Hz

② Pacemaker pulse generator; pulse amplitude 2.5 V, duration 2 ms and frequency of 1.7 Hz

NOTE Adjust pulse amplitude and duration as specified in 201.12.1.101.12 and 201.12.1.101.13.

Figure 201.114 – Pacemaker test circuit

201.12.1.101.14 Synchronizing pulse for cardioversion

If a pulse is available on a SIGNAL OUTPUT PART in order to synchronize a defibrillator discharge, the time interval from the R wave peak to the start of the synchronizing pulse shall not be greater than 35 ms. Pulse characteristics of amplitude, duration, shape and output impedance shall be disclosed in the ACCOMPANYING DOCUMENTS.

Check for compliance using the test circuit of Figure 201.105 and the waveform of Figure 201.113.

In Figure 201.105, open switch S1, close switches S and S2 and set S4 to position B. Connect the signal generator with the waveform of Figure 201.113 to the R (RA) LEAD WIRE. Connect all other LEAD WIRES to the N (RL) LEAD WIRE. Adjust the signal generator to a frequency of 1 Hz. Apply QRS amplitudes (a) of 0.5, 2.0 and 5.0 mV sequentially; For each amplitude (a) set the QRS duration d to 70 ms, 100 ms, 120 ms and to 40 ms for neonatal/pediatric ME EQUIPMENT.

Verify that the leading edge of the synchronizing pulse output occurs no later than 35 ms from the peak of the R wave of the input signal.

201.12.1.101.15 * Heart rate range, accuracy, and QRS detection range

ME EQUIPMENT shall be equipped with means to detect and display the heart rate.

The heart rate display range shall be at least 30/min to 200/min for adults and 30/min to 250/min for neonatal and pediatric use. The accuracy of the detected heart rate shall be ±10% or ±5/min, whichever is greater. ECG input signals at rates that are lower than the specified lower display range limit shall not indicate a heart rate greater than this lower limit. ECG input signals at rates above the upper limit of the specified display range, up to 300/min for adults and 350/min for neonatal and pediatric use shall not detect heart rates lower than 300/min for adults and 350/min for neonatal and pediatric use.

The minimum detection range of QRS amplitudes (a in Figure 201.113) shall be 0.5 mV to 5 mV for durations of the QRS wave between 70 ms and 120 ms (40 ms and 120 ms for neonatal/pediatric ME EQUIPMENT). For ME EQUIPMENT set for adult PATIENTS, the heart rate meter shall not respond to ECG signals having a QRS amplitude of 0.15 mV or less, or a duration of 10 ms or less with an amplitude of 1 mV. Response to either or both of these types of signals is permitted in ME EQUIPMENT set for neonatal/pediatric PATIENTS.

Check for compliance using the test circuit of Figure 201.105 and the waveform of Figure 201.113.

Open switch S1, close switches S and S2 and set S4 to position B. With the signal generator apply the waveform of Figure 201.113 to the R (RA) LEAD WIRE with an amplitude (a) of 1 mV. For adult use, set the QRS duration (d) to 70 ms and to 120 ms. For neonatal or pediatric use, set the QRS duration (d) to 40 ms and 120 ms. Connect all other LEAD WIRES to the N (RL) LEAD WIRES. Set the GAIN to 10 mm/mV and the sweep speed to 25 mm/s.

Slowly vary the input signal heart rate from zero to 30/min pausing every 10/min to allow the displayed heart rate to stabilize. The displayed heart rate for values within the specified display range shall be within ± 5/min. For input signal rates below the specified low limit, the displayed heart rate shall not exceed the specified low limit.

Apply a signal rate of 300/min, and a signal rate that is one-half the sum of 300/min and the specified maximum rate. For neonatal/pediatric use, these rates are 350/min and a signal rate one-half the sum of 350/min and the specified maximum rate. The displayed heart rate shall not be less than the specified upper limit of the display range.

Accuracy requirements:

Vary the input signal rate from 0/min to 200/min for adult use and to 250/min for neonatal or pediatric use. Use intermediate input signal rates of 30/min, 60/min, 120/min, and 180/min. The displayed heart rate shall be within ± 10 % or ± 5/min, whichever is greater, of the input signal rate.

Repeat the test with amplitudes (a) of the input signal of Figure 201.113, 0.5 mV, 2.0 mV, and 5.0 mV. For each amplitude (a), set the QRS duration (d) in Figure 201.113 to 70 ms, 100 ms, and to 120 ms for adult use. For neonatal or pediatric use, set the QRS durations (d) to 40 ms, 80 ms, and 120 ms.

Repeat the test in adult mode with a QRS amplitude of 0.15 mV and afterwards with a QRS duration of 10 ms and a QRS amplitude of 1 mV.

The accuracy requirements described above shall be met. In adult mode, the ME EQUIPMENT shall not count the heart rate when a QRS amplitude of 015 mV is applied and when a QRS duration of 10 ms and a QRS amplitude of 1 mV is applied.

Place a sinusoidal voltage of 100 μV peak-to-valley at mains frequency in series with the signal generator of Figure 210.105. Set the amplitude (a) of the waveform in Figure 201.113 to 1 mV and its duration (d) to 100 ms with a repetition rate of 80/min. Ensure that the line frequency notch filter, if provided, is on for the test. Vary the input signal rates as described above. The indicated rate shall meet the accuracy requirements.

201.12.1.101.16 * Channel height and aspect ratio

The output display of the ME EQUIPMENT shall accommodate the ECG signals specified in 201.12.1.101.2, and shall comply with the following additional requirements.

a) **Channel height.** ME EQUIPMENT shall provide means to display an ECG signal that meets the following requirements.

   For PERMANENT DISPLAYS, within a vertical space of at least 20 mm per ECG channel.

   For NON-PERMANENT DISPLAYS, within a vertical space of at least:

   – 10 mm per ECG channel for ME EQUIPMENT with an INTENDED USE that includes transport monitoring or being PATIENT worn.

   – 30 mm per ECG channel for ME EQUIPMENT with any other INTENDED USE.

   Other channel height selections may be provided.

   Compliance is checked as follows:

   Apply a sinusoidal or triangular test signal at any frequency between 1 Hz and 40 Hz. Adjust the input amplitude to produce an output deflection covering the expected full channel height of the output display area for the ECG channel being tested. Verify that the amplitude is no less than the value indicated above depending on the INTENDED USE for that type of PERMANENT DISPLAY or NON-PERMANENT DISPLAY. Repeat this test for each provided ECG channel. Verify alternate channel heights in a similar fashion.

b) **Aspect ratio.** The aspect ratio of PERMANENT and NON-PERMANENT DISPLAYS shall be (0.4 ± 0.08) s/mV, where aspect ratio is defined as the ratio of vertical GAIN (in mm/mV) to sweep speed (in mm/s). For ME EQUIPMENT providing several different aspect ratios or adjustable aspect ratios, an aspect ratio of (0.4 ± 0.08) s/mV shall be among those provided (at 10 mm/mV and 25 mm/s, the aspect ratio is 0.4).

   Compliance is checked as follows:

   Apply a 1 mV peak-to-valley sinusoidal or triangular signal at a frequency of 1.0 Hz. Measure the amplitude of the displayed signal (A) in mm peak-to-valley. Measure the length (B) in mm along the display for one complete waveform cycle. The ratio A/B must be 0.4 ± 0.08.

201.12.1.101.17 Tall T-wave rejection capability

Disclosure shall be made of the maximum T-wave amplitude (a_T) for which heart rate indication is within the error limits specified in 201.12.1.101.15. If the maximum T-wave amplitude (a_T) that can be rejected is affected by bandwidth chosen, also disclose separately the maximum T-wave amplitude rejected for each bandwidth.

Use a QRS test signal (Figure 201.110) of 1 mV amplitude (a) and 100 ms duration (d), with a heart rate of 80/min, a T-wave (positive half of a sine wave) duration (d_T) of 180 ms, and QT interval (d_{QT}) of 350 ms. Allow ME EQUIPMENT to stabilize for at least 20 s before testing.

201.12.3 Alarm systems

Addition:

ME EQUIPMENT shall be equipped with an ALARM SYSTEM as specified in Clause 208 of this particular standard.

201.12.4 Protection against hazardous output

201.12.4.101.1 Indications on PERMANENT DISPLAYS and NON-PERMANENT DISPLAYS

ECG related clinical OPERATOR settings that may affect the interpretation of ECG waveforms shall be indicated on PERMANENT DISPLAYS and NON-PERMANENT DISPLAYS. At least the following settings shall be indicated:

a) any filter settings;

b) selected LEAD/S;

c) GAIN INDICATOR (see 201.12.1.101.9);

d) sweep speed (on PERMANENT DISPLAYS only);

NOTE ECG waveforms presented on PERMANENT DISPLAYS appear on a g rid (see IEC 60601-2-25 subclause 201.12.4.109.4.5).

201.13 HAZARDOUS SITUATIONS and fault conditions

Clause 13 of the general standard applies.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard applies.

201.15 Construction of ME EQUIPMENT

Clause 15 of the general standard applies, except as follows:

201.15.3.4 Drop test

Addition:

201.15.3.4.101 * ELECTRODES and PATIENT CABLES

ELECTRODES and PATIENT CABLES, which contain electronic components, shall not present a HAZARDOUS SITUATION and shall continue functioning normally after falling freely from a height of 1 m onto a hard surface.

Testing need not be performed if examination of the construction and circuit arrangement shows that no HAZARDOUS SITUATION is possible and that normal function will not be impaired.

Compliance is checked by the following test:

Allow the test sample to fall freely once from each of three different starting attitudes from a height of 1 m onto a 50 mm thick hardwood board (for example, hardwood >700 kg/m³), which lies flat on a rigid base (concrete block).

After this test, no parts shall become accessible that exceed the values of the LEAKAGE CURRENTS when touched with the test finger. Cracks not visible to the naked eye and surface cracks in fiber-reinforced moldings and the like shall be ignored. After this test all requirements of this particular standard shall be satisfied and the ME EQUIPMENT shall function normally.

201.15.4.4 Indicators

Addition:

201.15.4.4.101 Indicator of battery operation and battery status

ME EQUIPMENT shall visually indicate when it is operating from its INTERNAL ELECTRICAL POWER SOURCE, unless it is only INTERNALLY POWERED.

INTERNALLY POWERED ME EQUIPMENT shall visually indicate its remaining battery capacity when operating from its INTERNAL ELECTRICAL POWER SOURCE.

Compliance is checked by inspection and measurement.

201.16 ME SYSTEMS

Clause 16 of the general standard applies.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Clause 17 of the general standard applies, except as follows:

See Clause 202.

202 Electromagnetic compatibility – Requirements and tests

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

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

Addition:

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

202.6 ELECTROMAGNETIC COMPATIBILITY

202.6.1 EMISSIONS

202.6.1.1.2 Tests

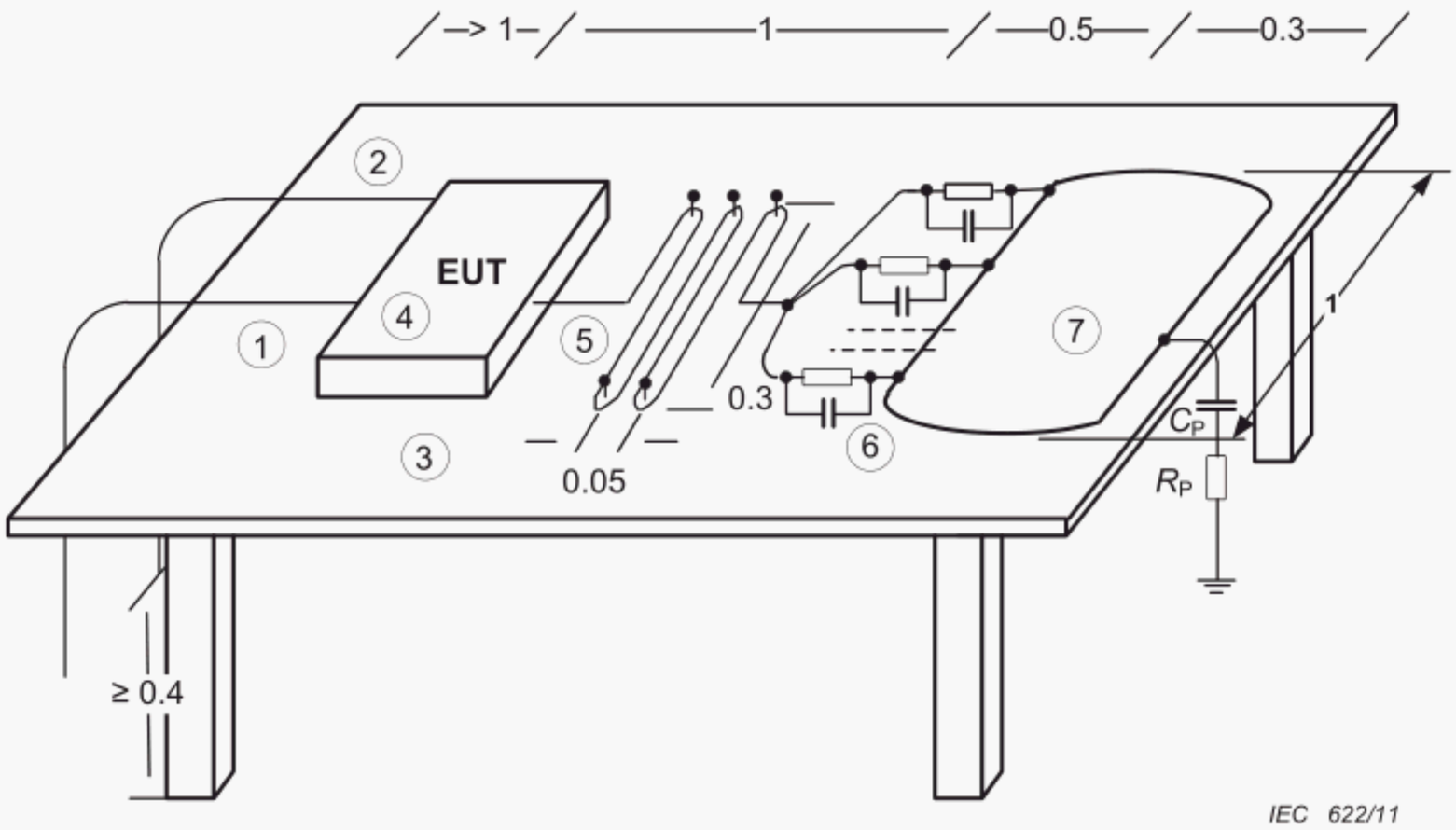
a) PATIENT cables

Replacement:

ME EQUIPMENT shall be tested with the PATIENT CABLE(S) as specified by the MANUFACTURER with all SIP/SOP cables connected to ME EQUIPMENT (see Figure 202.101); the distances of SIP/SOP cables between the open end and floor (ground plane) shall be ≥ 40 cm. If the MANUFACTURER specifies PATIENT CABLES with different lengths only one representative sample of each length has to be tested.

The RC network (C_P, R_P) and the metal plate (7) of Figure 202.101 are not used during radiated emissions testing.

Dimensions in m



Components

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

C_P 220 pF
R_P 510 Ω

C_P in series with R_P simulates the body of the PATIENT.

The RC network (C_P, R_P), the load simulating the PATIENT (6), and the metal plate (7) must not be used during radiated EMISSIONS testing.

Figure 202.101 – Test layout for radiated and conducted EMISSION test and radiated immunity test
(see 202.6.1.1.2 a) and 202.6.2.1.10)

202.6.2 IMMUNITY

202.6.2.1.10 Compliance criteria

Addition:

ME EQUIPMENT shall comply with subclause 6.2.1.10 of IEC 60601-1-2:2007 and the accuracy of the detected heart rate shall be ± 10% or ±5/min, whichever is greater (see subclause 201.12.1.101.15) except subclauses 202.6.2.2.1 and 202.6.2.101 in this particular standard.

202.6.2.2 ELECTROSTATIC DISCHARGE (ESD)

202.6.2.2.1 Requirements

Addition:

ME EQUIPMENT may show temporary DEGRADATION during discharges. Within 10 s the ME EQUIPMENT shall resume normal operation in the previous operating mode, without loss of any OPERATOR settings or stored data, and shall continue to perform its intended function and maintain ESSENTIAL PERFORMANCE (see 202.6.2.1.10).

202.6.2.3 Radiated RF electromagnetic fields

202.6.2.3.1 Requirements

Addition to item a):

IMMUNITY TEST LEVEL of 3 V/m applies.

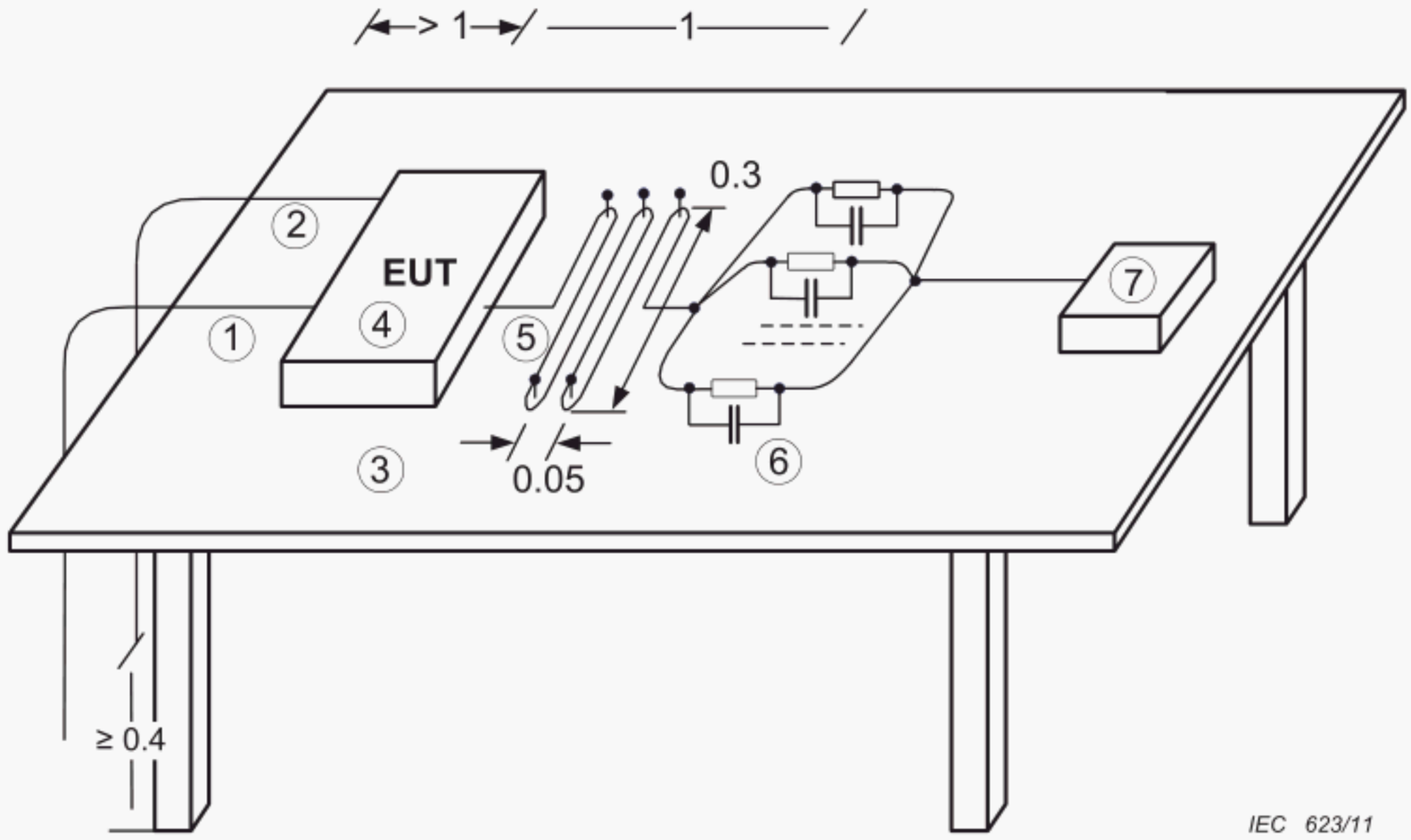
202.6.2.3.2 Tests

Addition:

aa) Any SIGNAL INPUT/OUTPUT PART cable and POWER SUPPLY CORD are arranged generally as in Figure 202.102. Maintain distances of ≥ 40 cm between SIP/SOP cables and the floor (ground plane).

bb) Perform the test using the simulated input signal of Figure 201.113 with an amplitude (a) of 1 mV, a duration (d) of 100 ms and a heart rate of 100 1/s.

Dimensions in m



Components

① Mains cable

② Signal cable

③ Table made of insulating material

④ ME EQUIPMENT under test

⑤ PATIENT CABLE

⑥ Load simulating the PATIENT (51 kΩ in parallel with 47 nF)

⑦ ECG simulator (shielded and, if necessary, low pass filtered, if susceptible to radio frequency interference)

Figure 202.102 – Set-up for radiated IMMUNITY test
(see 202.6.2.3.2)

202.6.2.4 Electrical fast transients and bursts

202.6.2.4.1 Requirements

Addition:

When exposed to electrical fast transients and bursts, via the POWER SUPPLY CORD, the ME EQUIPMENT shall continue to display the heart rate. The accuracy of the displayed heart rate shall be ± 10% or ±5/min, whichever is greater (see subclause 201.12.1.101.15).

Testing of PATIENT CABLES and interconnecting cables specified to be more than 3 m in length may show temporary DEGRADATION during exposure of fast transients and bursts. Within 10 s the ME EQUIPMENT shall resume normal operation in the previous operating mode, without loss of any OPERATOR settings or stored data, and shall continue to display the heart rate. The accuracy of the displayed heart rate shall be ± 10% or ±5/min, whichever is greater (see subclause 201.12.1.101.15).

202.6.2.4.2 Tests

Addition:

aa) Position ME EQUIPMENT 0.8 m ± 0.08 m above the reference ground plane.

bb) Use the power cord provided with the ME EQUIPMENT to connect ME EQUIPMENT to the output of the EFT/B generator.

cc) Perform the test using the simulated input signal of Figure 201.113 with an amplitude (a) of 1 mV, a duration (d) of 100 ms and a heart rate of 100 1/s.

202.6.2.6 Conducted disturbances, induced by RF fields

202.6.2.6.1 Requirements

Addition:

aa) When exposed to a conducted radio frequency voltage, via the POWER SUPPLY CORD, the ME EQUIPMENT shall continue to perform its intended function as described in 202.6.2.1.10.

bb) *PATIENT CABLES are exempt from this requirement.

202.6.2.6.2 Tests

Addition:

aa) Subclause 6.2.6.2, items c) and e) of IEC 60601-1-2:2007 do not apply.

Addition:

202.6.2.101 * Electrosurgery interference

ECG telemetry systems are excluded from this test.

Means shall be provided to protect against malfunction caused by electrosurgery. Perform the test below, using any PATIENT CABLES, LEAD WIRES, ACCESSORIES or settings recommended by the MANUFACTURER.

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

Compliance is checked according to Figures 202.103 and 202.104.

Use HF SURGICAL EQUIPMENT which complies with IEC 60601-2-2 and has a minimum power cut mode capability of 300 W, a minimum coagulation mode capability of 100 W and working frequency of 400 kHz ±10 %.

a) Test in cut mode:

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

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

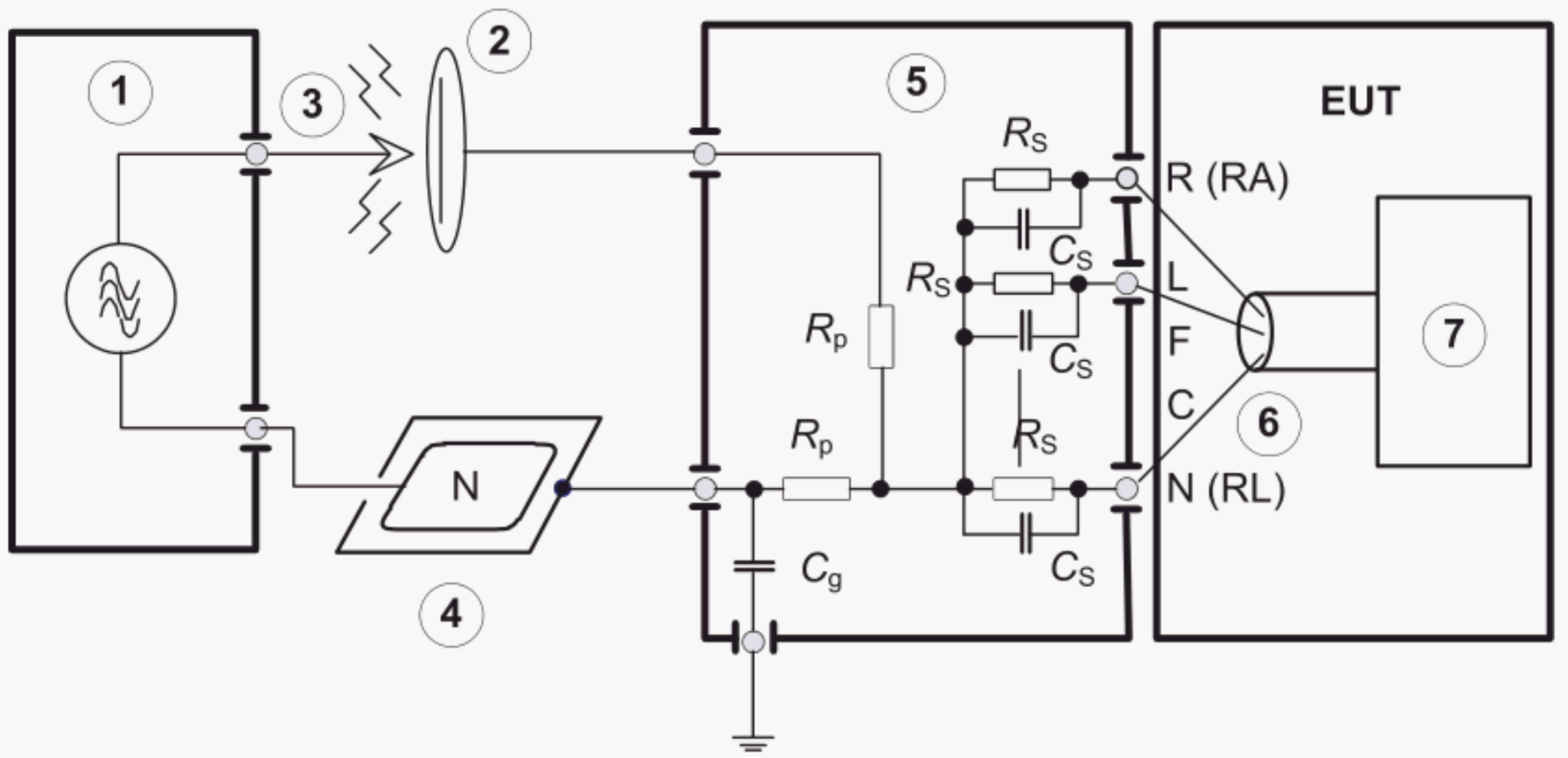
Verify whether the ECG baseline returns within 10 s to its normal position and the ME EQUIPMENT returns to the previous operating mode without loss of any stored data.

Repeat the procedure five times.

b) *Test in coagulation mode:*

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

Test of the spray coagulation mode is excluded.



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Components

① HF SURGICAL EQUIPMENT

② Metal plate

③ ACTIVE ELECTRODE of the HF SURGICAL EQUIPMENT

④ Metal plate/neutral electrode (N) of HF SURGICAL EQUIPMENT

⑤ Coupling network

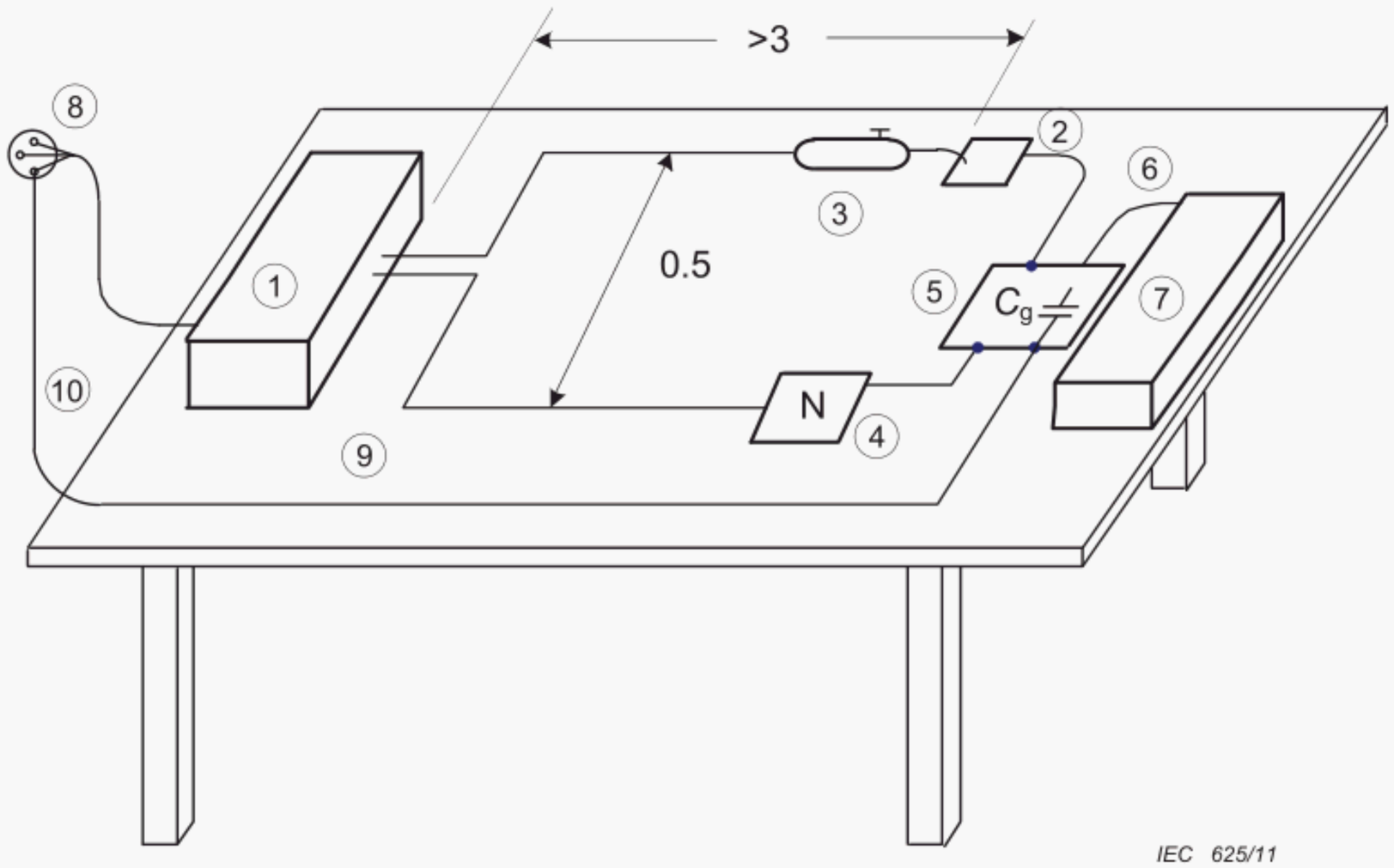
⑥ PATIENT CABLE

⑦ ME EQUIPMENT

R_p 500 Ω, 200 W (low-inductive, < 5 μH, simulates patient impedance)
C_g 47 nF (to minimize the effect of different types of HF SURGICAL EQUIPMENT designs)
R_s 51 kΩ R_s//C_s simulate the skin impedance
C_s 47 nF
R, L, F, C, N LEAD WIRES according to Table 201.103

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

Figure 202.103 – Test circuit for HF surgery protection measurement
(see to 202.6.2.101)



IEC 625/11

Components

① HF SURGICAL EQUIPMENT

② Metal plate

③ ACTIVE ELECTRODE of the HF SURGICAL EQUIPMENT

④ Neutral electrode of the HF SURGICAL EQUIPMENT

⑤ Coupling network – test set-up according to item 5 in Figure 201.103

⑥ PATIENT CABLE

⑦ ME EQUIPMENT under test

⑧ SUPPLY MAINS

⑨ Table made of insulating material

⑩ Connection to PROTECTIVE EARTH CONDUCTOR for grounding

Figure 202.104 – Test setup for HF surgery protection measurement
(see to 202.6.2.101)

208 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

IEC 60601-1-8:2006 applies except as follows (see also alarm diagrams in Annex BB):

208.6 ALARM SYSTEMS

208.6.1 ALARM CONDITION

208.6.1.2 * ALARM CONDITION priority

Addition:

ME EQUIPMENT that includes in its INTENDED USE monitoring of PATIENTS that are not continuously attended by a clinical OPERATOR in NORMAL USE shall treat ALARM CONDITIONS that may result in

minor injury and delayed onset of potential HARM as LOW PRIORITY ALARM CONDITIONS (see Table 208.101).

The ACCOMPANYING DOCUMENTS shall describe how the RESPONSIBLE ORGANIZATION may enable or disable auditory ALARM SIGNALS for LOW PRIORITY ALARM CONDITIONS. The requirements of 6.7 of IEC 60601-1-8:2006 apply.

NOTE This adaptation of Table 1 of IEC 60601-1-8:2006 necessitated an additional configuration capability for this ME EQUIPMENT. This capability is necessary when the RESPONSIBLE ORGANIZATION needs auditory ALARM SIGNALS for LOW PRIORITY ALARM CONDITIONS such as for intensive care units when central monitoring is not being used.

Table 208.101 modifies Table 1 – ALARM CONDITION priorities, for ME EQUIPMENT that includes in its INTENDED USE monitoring of PATIENTS that are not continuously attended by a clinical OPERATOR in NORMAL USE:

Table 208.101 – ALARM CONDITION priorities *for ME EQUIPMENT that includes in its INTENDED USE monitoring of PATIENTS that are not continuously attended by a clinical OPERATOR*

Potential result of failure to respond to the cause of ALARM CONDITION	Onset of potential HARM [a]		
	Immediate [b]	Prompt [c]	Delayed [d]
Death or irreversible injury	HIGH PRIORITY [e]	HIGH PRIORITY	MEDIUM PRIORITY
Reversible injury	HIGH PRIORITY	MEDIUM PRIORITY	LOW PRIORITY
Minor injury or discomfort	MEDIUM PRIORITY	LOW PRIORITY	LOW PRIORITY

[a] Onset of potential HARM refers to when an injury occurs and not to when it is manifested.

[b] Having the potential for the event to develop within a period of time not usually sufficient for manual corrective action.

[c] Having the potential for the event to develop within a period of time usually sufficient for manual corrective action.

[d] Having the potential for the event to develop within an unspecified time greater than that given under “prompt”.

[e] Where practicable, ME EQUIPMENT with a therapeutic function incorporates automatic safety mechanisms to prevent immediate death or irreversible injury caused by the ME EQUIPMENT. See also appropriate particular standards.

208.6.3.3 Auditory ALARM SIGNALS

208.6.3.3.1 * Characteristics of auditory ALARM SIGNALS

Addition:

For ME EQUIPMENT that includes in its INTENDED USE monitoring of PATIENTS that are not continuously attended by a clinical OPERATOR in NORMAL USE:

– Auditory ALARM SIGNALS shall annunciate for LOW PRIORITY ALARM CONDITIONS (delete footnote “d” from Table 3 of IEC 60601-1-8:2006).

– Replace “> 15 s or no repeat” with “2.5 s to 30.0 s” in the “LOW PRIORITY ALARM SIGNAL” column of Table 3 of IEC 60601-1-8:2006.

– Auditory ALARM SIGNALS shall annunciate for TECHNICAL ALARM CONDITIONS.

Table 208.102 modifies Table 3 – Characteristics of the burst of auditory ALARM SIGNALS, for ME EQUIPMENT that includes in its INTENDED USE monitoring of PATIENTS that are not continuously attended by a clinical OPERATOR in NORMAL USE:

Table 208.102 – Characteristics of the BURST of auditory ALARM SIGNALS for ME EQUIPMENT that includes in its INTENDED USE monitoring of PATIENTS that are not continuously attended by a clinical OPERATOR

Characteristic	HIGH PRIORITY ALARM SIGNAL	MEDIUM PRIORITY ALARM SIGNAL	LOW PRIORITY ALARM SIGNAL
Number of PULSES in BURST [a, e]	10	3	1 or 2
PULSE spacing (t_s) (see Table 208.101)			
between 1st and 2nd PULSE	x	y	y
between 2nd and 3rd PULSE	x	y	Not applicable
between 3rd and 4th PULSE	$2x + t_d$	Not applicable	Not applicable
between 4th and 5th PULSE	x	Not applicable	Not applicable
between 5th and 6th PULSE	0.35 s to 1.30 s	Not applicable	Not applicable
between 6th and 7th PULSE	x	Not applicable	Not applicable
between 7th and 8th PULSE	x	Not applicable	Not applicable
between 8th and 9th PULSE	$2x + t_d$	Not applicable	Not applicable
between 9th and 10th PULSE	x	Not applicable	Not applicable
INTERBURST INTERVAL [b, c] (t_b)	2.5 s to 15.0 s	2.5 s to 30.0 s	>15 s to 60 s
Difference in amplitude between any two PULSES	Maximum 10 dB	Maximum 10 dB	Maximum 10 dB

Where x shall be a value between 50 ms and 125 ms.

Where y shall be a value between 125 ms and 250 ms.

The variation of x and y within a BURST shall be ± 5 %.

MEDIUM PRIORITY $t_d + y$ shall be greater than or equal to HIGH PRIORITY $t_d + x$.

[a] See also Table 4 of IEC 60601-1-8:2006 for characteristics of the PULSE.

[b] Unless otherwise specified in a particular standard for a particular ME EQUIPMENT.

[c] MANUFACTURERS are encouraged to use the longest INTERBURST INTERVAL consistent with the RISK ANALYSIS. Writers of particular standards are encouraged to consider the longest appropriate INTERBURST INTERVAL of the auditory ALARM SIGNAL for the particular ALARM SYSTEM application. Long INTERBURST INTERVALS can under certain conditions negatively affect the ability to correctly discern, in a timely manner, the source of the ALARM CONDITION.

[e] Unless inactivated by the clinical OPERATOR, MEDIUM PRIORITY and LOW PRIORITY auditory ALARM SIGNALS shall complete at least one BURST, and HIGH PRIORITY auditory ALARM SIGNALS shall complete at least half of one BURST.

The ACCOMPANYING DOCUMENTS shall describe how the RESPONSIBLE ORGANIZATION may enable or disable auditory ALARM SIGNALS for LOW PRIORITY ALARM CONDITIONS and may restrict access to control over the INTERBURST INTERVAL for all auditory ALARM SIGNALS. The requirements of 6.7 of IEC 60601-1-8:2006 apply.

NOTE This adaptation of Table 3 of IEC 60601-1-8:2006 necessitated an additional configuration capability for this ME EQUIPMENT. This capability is necessary when the RESPONSIBLE ORGANIZATION needs auditory ALARM SIGNALS for LOW PRIORITY ALARM CONDITIONS such as for intensive care units when central monitoring is not being used.

RISK MANAGEMENT shall be applied to determine the maximum INTERBURST INTERVAL for auditory ALARM SIGNALS associated with HIGH, MEDIUM, and LOW PRIORITY ALARM CONDITIONS.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

208.6.3.3.2 Volume of auditory ALARM SIGNALS and INFORMATION SIGNALS

Addition:

208.6.3.3.2.101 * Volume of auditory ALARM SIGNALS reducible to zero

If the clinical OPERATOR reduces the volume of auditory ALARM SIGNALS to zero (no sound pressure), the ALARM SIGNAL'S inactivation state AUDIO OFF shall be indicated, unless ME EQUIPMENT is part of a DISTRIBUTED ALARM SYSTEM where the ALARM SIGNALS are repeated at remote components of a DISTRIBUTED ALARM SYSTEM.

Compliance is checked by functional test.

208.6.4.2 * Delays to or from a DISTRIBUTED ALARM SYSTEM

Addition:

The ALARM SIGNAL GENERATION DELAY of PHYSIOLOGICAL ALARM CONDITIONS and TECHNICAL ALARM CONDITIONS at remote components of a DISTRIBUTED ALARM SYSTEM shall be limited so that PATIENT treatment is not unacceptably delayed. RISK MANAGEMENT shall be applied to determine the maximum ALARM SIGNAL delay time that is acceptable before presentation of ALARM SIGNALS at remote components of a DISTRIBUTED ALARM SYSTEM.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

208.6.6 ALARM LIMIT

208.6.6.2 Adjustable ALARM LIMIT

Addition:

208.6.6.2.101 Adjustment range of heart rate ALARM LIMITS

ME EQUIPMENT shall be equipped with means to adjust upper and lower heart rate ALARM LIMITS. For adult PATIENTS, the upper ALARM LIMIT settings shall be adjustable to at least between 100/min and 200/min and the lower ALARM LIMIT settings shall be adjustable at least between 30/min and 100/min. For neonatal and pediatric PATIENTS, the upper ALARM LIMIT settings shall be adjustable at least between 100/min and 250/min and the lower ALARM LIMIT settings shall be adjustable at least between 30/min and 150/min.

Compliance is checked by inspection.

208.6.6.2.102 Resolution of ALARM LIMIT settings

The ALARM LIMIT settings shall be adjustable in steps not exceeding ±5/min.

Compliance is checked by inspection.

208.6.6.2.103 Time to alarm for heart rate ALARM CONDITIONS

The ALARM SIGNAL GENERATION DELAY for cardiac standstill (asystole) shall not exceed 10 s.

The sum of ALARM CONDITION DELAY and ALARM SIGNAL GENERATION DELAY for ALARM SIGNALS for low heart rate or high heart rate ALARM CONDITIONS shall not exceed 10 s.

Compliance is checked by the following tests:

For all tests, a simulated ECG signal of 1 mV QRS amplitude and 70 ms QRS duration is applied. The deviation of the input heart rate from the nominal value shall be less than 5 %.

Low heart rate ALARM CONDITION: Set the heart rate to 80/min and the lower ALARM LIMIT to 60/min. Change the heart rate in a step function manner from 80/min to 40/min. Measure the time interval between the heart rate change and when the ALARM SIGNALS indicate that low limit ALARM CONDITION.

High heart rate ALARM CONDITION: Set the heart rate to 80/min and the upper ALARM LIMIT to 100/min. Change the heart rate in a step function manner from 80/min to 120/min. Measure the time interval between the heart rate change and when ALARM SIGNALS indicate that high limit ALARM CONDITION.

Cardiac standstill: Set the heart rate to 80/min and the lower ALARM LIMIT to 60/min. Change the heart rate in a step function manner from 80/min to 0/min. Measure the time interval between the heart rate change and when ALARM SIGNALS indicate the cardiac standstill ALARM CONDITION.

208.6.6.2.104 * TECHNICAL ALARM CONDITION indicating inoperable ME EQUIPMENT

ME EQUIPMENT shall be provided with means to indicate within 10 s that the ME EQUIPMENT is inoperable due to an overload or saturation of any part of the ECG amplifier and due to disconnected ECG LEAD WIRES.

Compliance is checked by the following test using the test circuit of Figure 201.105.

Set the GAIN to 10 mm/mV and the sweep speed to 25 mm/s. Close switches S, S2 and set S4 in position B. Connect the signal generator between the R (RA) LEAD WIRE and all other LEAD WIRES connected to the N (RL) LEAD WIRE. 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, increase the d.c. voltage at a rate of approximately 1 V/s in increments from 0 V to +5 V and –5 V, using any deblocking facility of the ME EQUIPMENT to restore the trace.

If the 10 Hz signal is not visible within 10 s, with an amplitude of at least 0.5 mV referred to the input, verify that a TECHNICAL ALARM CONDITION indicates that the ME EQUIPMENT is inoperable.

Disconnect all LEAD WIRES. Verify that within 10 s a TECHNICAL ALARM CONDITION indicates that the ME EQUIPMENT is inoperable.

208.6.6.2.105 Assignment of ALARM CONDITION priority

ALARM SIGNALS of heart rate ALARM CONDITIONS shall be at least of MEDIUM PRIORITY. The PHYSIOLOGICAL ALARM CONDITIONS cardiac standstill (asystole), ventricular tachycardia and ventricular fibrillation shall be of HIGH PRIORITY. Priorities of other PHYSIOLOGICAL

ALARM CONDITIONS such as arrhythmias (VPCs, ventricular bigeminy or irregular HR etc.) or whether those events may be treated as INFORMATION SIGNALS shall be determined by RISK MANAGEMENT.

Compliance is checked by inspection and functional tests.

208.6.8 ALARM SIGNAL inactivation states

Addition:

208.6.8.101 * TECHNICAL ALARM CONDITIONS

Inactivation of ALARM SIGNALS (ALARM PAUSED, and ALARM OFF)

a) shall not inactivate visual ALARM SIGNALS of TECHNICAL ALARM CONDITIONS that identify the specific ALARM CONDITION and its priority at a distance of 1 m from the ME EQUIPMENT;
b) may inactivate the visual ALARM SIGNAL specified in subclause 6.3.2.2 b) of IEC 60601-1-8.

In the case of a TECHNICAL ALARM CONDITION the any measured value(s) of the parameter(s) shall be displayed in such a way that the validity of the measured value(s) can be identified by the clinical OPERATOR.

NOTE During a TECHNICAL ALARM CONDITION, the physiological parameter(s) might not be capable of detecting PHYSIOLOGICAL ALARM CONDITIONS.

If LEAD WIRES, PATIENT CABLE or modules are intentionally disconnected by the clinical OPERATOR as specified by the MANUFACTURER, ALARM RESET may be used to disable the visual ALARM SIGNAL of those TECHNICAL ALARM CONDITIONS. Such means shall be documented in the instructions for use (see subclause 201.7.9.2.9.101 a) 14).

Compliance is checked by inspection and functional tests.

208.6.9 * ALARM RESET

Replacement:

Means shall be provided for the clinical OPERATOR to activate ALARM RESET of ALARM SIGNALS.

After activation of the ALARM RESET function

a) the auditory ALARM SIGNALS of PHYSIOLOGICAL ALARM CONDITIONS shall cease, enabling the ALARM SYSTEM to respond to a subsequent ALARM CONDITION.
b) visual ALARM SIGNALS for LATCHING ALARM CONDITIONS that no longer exist shall cease (see 201.7.9.2.9.101 14) and 208.6.8.101)).
c) visual ALARM SIGNALS for any existing ALARM CONDITIONS shall continue as long as those ALARM CONDITIONS exist.
d) the ALARM SYSTEM shall be enabled immediately so that it can respond to a subsequent ALARM CONDITION.
e) the visual ALARM SIGNALS of TECHNICAL ALARM CONDITIONS shall not cease as long as the technical ALARM CONDITION exists.

The means of control of ALARM RESET shall be marked with symbol IEC 60417-5309 (2002-10) (see IEC 60601-1-8-2006 symbol 2 of Table C.1) and/or with the text string of marking 5 in Table C.2.

Compliance is checked by inspection.

208.6.10 * NON-LATCHING and LATCHING ALARM SIGNALS

Addition to the first paragraph:

For ME EQUIPMENT that supports mixtures of LATCHING ALARM SIGNALS and NON-LATCHING ALARM SIGNALS, means shall be provided that allows the RESPONSIBLE ORGANIZATION to configure ME EQUIPMENT to have all LATCHING ALARM SIGNALS or all NON-LATCHING ALARM SIGNALS for PHYSIOLOGICAL ALARM CONDITIONS and to restrict access to this configuration to the RESPONSIBLE ORGANIZATION.

NOTE This requirement adds an additional configuration capability for use in intensive care units where the RESPONSIBLE ORGANIZATION needs LATCHING ALARM SIGNALS for all ALARM CONDITIONS.

Compliance is checked by functional test

Addition:

208.6.10.101 * NON-LATCHING ALARM SIGNALS for TECHNICAL ALARM CONDITIONS

NON-LATCHING ALARM SIGNALS shall be assigned to TECHNICAL ALARM CONDITIONS.

208.6.11 DISTRIBUTED ALARM SYSTEM

208.6.11.2.2 * Failure of remote communication of ALARM CONDITIONS

Replacement of item b):

b) shall create a TECHNICAL ALARM CONDITION in any affected parts of the DISTRIBUTED ALARM SYSTEM that can generate ALARM SIGNALS.

Addition:

If, while the ME EQUIPMENT is in the AUDIO OFF state, the ME EQUIPMENT detects a communication failure with the DISTRIBUTED ALARM SYSTEM, it shall terminate the AUDIO OFF state and shall initiate a TECHNICAL ALARM CONDITION.

Additional subclause:

208.6.11.101 * Inactivation/activation of ALARM SIGNALS at remote components of a DISTRIBUTED ALARM SYSTEM

If deemed acceptable by RISK MANAGEMENT for its intended environment of use, ME EQUIPMENT may be provided with means for the clinical OPERATOR to activate and inactivate ALARM SIGNALS of the ME EQUIPMENT or to change ALARM LIMIT SETTINGS from remote components of a DISTRIBUTED ALARM SYSTEM by:

– enabling any inactivation states that are configured on t he ME EQUIPMENT (ALARM PAUSED, AUDIO PAUSED, ALARM OFF or AUDIO OFF) and activating the function ALARM RESET and

– termination of the inactivation state.

ME EQUIPMENT that provides means to remotely activate and inactivate ALARM SIGNALS shall also provide means to configure (enable or disable) remote inactivation/activation for every provided inactivation state. To prevent the clinical OPERATOR from changing that configuration, such means shall be restricted to the RESPONSIBLE ORGANIZATION (see 6.7 of IEC 60601-1-8:2006).

Compliance is checked by inspection.

Annexes

The annexes of the general standard apply.

Annex AA
(informative)

Particular guidance and rationale

AA.1 Use with defibrillator

This category of ME EQUIPMENT is likely to be used in the intensive monitoring of the critically ill and particularly in coronary care units, environments in which the use of defibrillators is to be expected.

Defibrillator protection is required not only from the safety point of view but also, as this ME EQUIPMENT gives the first indication of the restoration of sinus rhythm, from the performance point of view (see 201.8.5.5.1).

The Working Group was thus in no doubt that not only must defibrillator protection be made a requirement in this ME EQUIPMENT, but that the ME EQUIPMENT also shall show a reasonable trace within a short time to indicate to the clinician or user the outcome of the defibrillation action. Subclause 201.8.5.5.1 calls for a visible trace within 5 s of the defibrillation action and this requirement includes the recovery of the ELECTRODES.

AA.2 Rationale for defibrillator test voltages

AA.2.1 General

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

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

If the ELECTRODE of an item of ME EQUIPMENT is applied to the thorax or trunk of this PATIENT, roughly within the compass of the defibrillator paddles, the voltage to which such an ELECTRODE is subjected depends on its position but will generally be less than the on-load defibrillator voltage. Unfortunately, it is not possible to say how much less, as the ELECTRODE in question may be placed anywhere in this area, including immediately adjacent to one of the defibrillator paddles. For safety, it must therefore be required that such an ELECTRODE and the ME EQUIPMENT to which it is connected shall be able to withstand the full defibrillator voltage. This must be the no-load voltage, as one of the defibrillator paddles may not be making good contact with the PATIENT.

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

The last set of circumstances to be considered is when the ELECTRODE is connected to the PATIENT outside the compass of the defibrillator paddles, such as on the PATIENT'S arm or shoulder. The only safe assumption here is that no voltage-dividing effect takes place, and the arm or shoulder effectively becomes an open-ended electrical conductor connected to the nearer defibrillator paddle. The ELECTRODE and associated ME EQUIPMENT have to be able to withstand the full no-load voltage of the defibrillator.

In this discussion, as in the requirements of this particular standard, it is assumed that one of the defibrillator paddles is connected to earth.

AA.2.2 Summary

Table AA.1 lists typical examples of electrode positions and resulting voltages that may develop between these electrodes during a defibrillator discharge. Under worst case conditions the full no-load defibrillator voltage is applied between ELECTRODES.

Table AA.1 – Electrode positions and electrical strength requirements

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

AA.2.3 Specific requirement

For this particular standard, the first and the third conditions from Table AA.1 apply. Monitoring ELECTRODES are usually placed on the PATIENT'S chest, shoulders or back but may also be placed on the patient's limbs. The ME EQUIPMENT therefore is subjected to a test voltage of 5 kV.

AA.3 Guidance and rationale for particular clauses

Several clauses from the second edition of IEC 60601-2-27 were eliminated because those clauses were incorporated in IEC 60601-1:2005.

Subclause 201.1.1 – Scope

The scope of this particular standard is defined as to include ME EQUIPMENT most commonly used for acquiring data from the PATIENT'S body.

Subclause 201.5.8 – Sequence of tests

Tests of 8.5.5 are performed first so that the tests of LEAKAGE CURRENT and dielectric strength may show any DEGRADATION in the protective means. Tests of 201.12.1.101.16 b), 201.12.1.101.7 and 201.12.1.101.9 are performed before the tests for the remaining subclauses of 201.12.1.101 to identify the vertical conversion factor determined in 201.12.1.101.7 needed for many of those tests.

Subclause 201.6.2 – Protection against electric shock

ME EQUIPMENT may be used in intracardiac procedures. Additionally, ME EQUIPMENT is frequently part of MULTIFUNCTION PATIENT MONITORING EQUIPMENT in which some or many other medical devices are connected to the same patient (ME SYSTEM). Therefore, reference to TYPE B and TYPE BF APPLIED PARTS is deleted.

Subclause 201.7.9.2.9.101 a) 4) – Additional instructions for use

The MANUFACTURER should describe the need to pay special attention to the type of ELECTRODES used, since some ELECTRODES may be subject to large offset potentials due to polarization. Recovery time after application of defibrillator pulses may be especially compromised. Squeeze bulb electrodes commonly used for diagnostic ECG recording may be particularly vulnerable to this effect. Also, a clear warning should provided that ELECTRODES of dissimilar metals should not be used unless the ELECTROCARDIOGRAPHIC MONITORING EQUIPMENT can handle polarization potentials as high as 1 Volt (V).

Subclause 201.7.9.2.9.101 a) 7) – Additional instructions for use

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

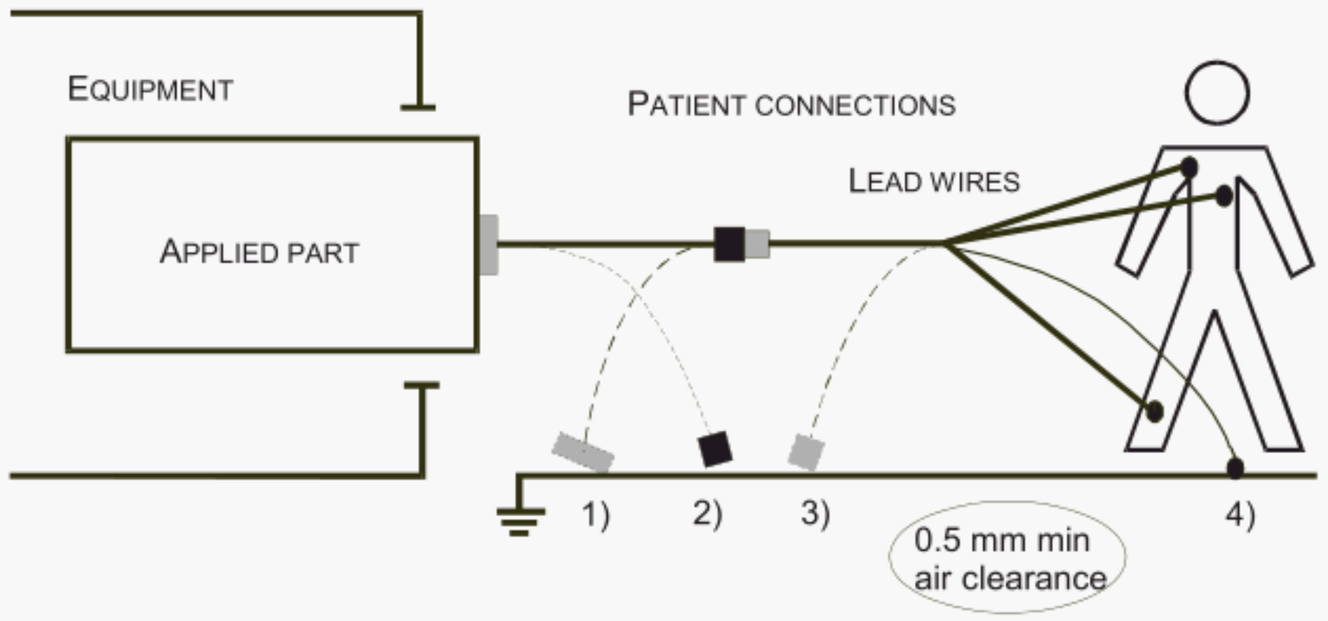
Subclause 201.8.5.2.3 – PATIENT leads

This requirement guards against two HAZARDOUS SITUATIONS: Firstly there shall be no possibility of an accidental PATIENT-to-earth connection via any LEAD WIRES, which may become detached from an ELECTRODE. Secondly there shall be no possibility of connecting the PATIENT accidentally to any live parts or hazardous voltages.

This means that for all ME EQUIPMENT, LEAD WIRES having exposed metal pin connectors, such as banana plugs, are not permissible. To meet the requirements of this particular standard, the connectors on LEAD WIRES that connect to ELECTRODES shall have no exposed conductive parts or conductive parts that could contact earth. This requirement is fulfilled if the air clearance between connector pins and a flat surface is at least 0.5 mm. The minimum necessary air clearance of 0.5 mm ensures a reliable contact with ELECTRODES. This requirement does not apply to the ELECTRODES themselves.

For all other connectors of a PATIENT CONNECTION – except that part of the LEAD WIRES that is connected to an ELECTRODE – the requirements of 8.5.2.3 of the general standard apply.

Figure AA.1 illustrates the requirements and rationale of 201.8.5.2.3.



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Key

□ Conductive connection to the PATIENT illustrating 8.5.2.3 of the general standard: connectors remote to the PATIENT

■ Conductive connection to the PATIENT illustrating 201.8.5.2.3: connectors remote to the ME EQUIPMENT

Items 1 to 4 illustrate conductive connections to and from the PATIENT. Without protective means, disconnected conductive connections may earth the PATIENT.

1), 3) conductive connection to a PATIENT (8.5.2.3 of the general standard) - 1 mm/1,500 V if the connector is able to be plugged into a mains socket

2), 4) PATIENT-to-earth connection via the APPLIED PART (addition 201.8.5.2.3 of this particular standard) – 0.5 mm air clearance

Figure AA.1 – APPLIED PART with multiple PATIENT CONNECTIONS

Subclause 201.8.5.5.1 – Defibrillation protection

To determine whether an attempt to defibrillate a PATIENT was successful, the ME EQUIPMENT needs to quickly recover from the amplifier overload produced by the defibrillation pulse. A 5 s recovery time is considered to be satisfactory to verify the effectiveness of the defibrillation.

The 400 Ω current-limiting resistor in test circuit of Figure 11 in the general standard represents the resistance of body tissue between one defibrillator paddle and an ELECTRODE. This value was used since it is unlikely that both defibrillator ELECTRODES will contact ELECTRODES of the ME EQUIPMENT at the same time.

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

At the time of defibrillation, many different LEAD combinations may be in use, potentially exposing any of those LEADS to the defibrillation voltage. Therefore, the LEAD combinations shown in Table 201.103 must be tested. These combinations ensure that every ELECTRODE is tested and include the LEAD(S) most likely to be affected by the ELECTRODE(S) connected to point C.

With certain types of ELECTRODES, the discharge of a defibrillator through a PATIENT may produce large d.c. offset potentials that might disable the amplifier of the ME EQUIPMENT. While the display may appear to recover, the ECG amplifier may remain inoperative for some time. (The requirement of 208.6.6.2.104 draws attention to such a situation.) The apparent lack of cardiac activity could lead to incorrect treatment. This can be minimized by a suitable choice of ELECTRODES (see also AA.1 and AA.2).

Subclause 201.11.6.5 – Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS

Small-sized ME EQUIPMENT or smaller parts of ME EQUIPMENT may be mounted on IV poles or used close to the PATIENT. Such use close to the PATIENT makes it likely that the ME EQUIPMENT may accidentally get wet during NORMAL USE. After being wetted in NORMAL USE, the ME EQUIPMENT needs to continue to provide BASIC SAFETY and ESSENTIAL PERFORMANCE to continue monitoring the PATIENT.

Subclause 201.11.8 – Interruption of the power supply/SUPPLY MAINS to the ME EQUIPMENT

Interruptions of the SUPPLY MAINS for less than 30 s are mainly caused by switching to an emergency power supply. Such power interruptions are considered NORMAL USE and consequently should not result in HAZARDS to the PATIENT. When power returns, the ME EQUIPMENT needs to resume the same mode of operation and restore all OPERATOR settings and PATIENT data that were in use before the SUPPLY MAINS was interrupted. Examples of typical stored data that may impact PATIENT safety are operating mode, ALARM SETTINGS (volume of auditory ALARM SIGNAL, ALARM LIMITS, ALARM OFF, etc.), trend data, and pacemaker pulse rejection, if OPERATOR selectable. In contrast to these settings, the instantaneous heart rate or the displayed ECG waveform do not fall under stored data.

Subclause 201.11.8.101 – Protection against depletion of battery

A discharged battery may be simulated using a laboratory variable power supply set to a low voltage and a series impedance to represent the increased battery impedance normally found under these circumstances. The value of series impedance should be found by experiment.

Subclause 201.12.1.101 – ESSENTIAL PERFORMANCE of ME EQUIPMENT

More than 25 years ago, the Association for the Advancement of Medical Instrumentation (AAMI) published EC13, the first standard that included safety and performance requirements for ELECTROCARDIOGRAPHIC MONITORING EQUIPMENT. At that time, all ELECTROCARDIOGRAPHIC MONITORING EQUIPMENT were wall-mounted and had built-in displays. These two characteristics fundamentally affected several key performance requirements relating to how ECG waveforms were displayed.

ANSI/AAMI EC13 was substantially revised in both 1992 and 2002. The 1992 revision added several new performance requirements. The 2002 revision changed the EMC requirements, added tests for electrosurgical interference and clarified several other test methods. These revisions did not affect those display-related requirements.

The first edition of IEC 60601-2-27, which was published in 1994, focused on safety related requirements for ELECTROCARDIOGRAPHIC MONITORING EQUIPMENT. The second edition of IEC 60601-2-27, which was published in 2005, added requirements related to ESSENTIAL PERFORMANCE of ELECTROCARDIOGRAPHIC MONITORING EQUIPMENT. Many ESSENTIAL PERFORMANCE requirements of the second edition of IEC 60601-2-27 became harmonized with ANSI/AAMI EC13:2002.

Some of the presentation-related requirements that originated in the first edition of ANSI/AAMI EC13 have changed. For example, the requirement for a 30 mm channel height ensures that an ECG waveform is large enough to be seen from the foot of the PATIENT'S bed. Two major changes to market needs have made it increasingly difficult for ELECTROCARDIOGRAPHIC MONITORING EQUIPMENT to meet the requirements of the IEC 60601-2-27 and ANSI/AAMI EC13:2002:

– Many RESPONSIBLE ORGANIZATIONS now require a display size to meet their specific needs. Such ELECTROCARDIOGRAPHIC MONITORING EQUIPMENT works with any size display rather than with a single built-in display.
– Surface-mount technologies allow networked ELECTROCARDIOGRAPHIC MONITORING EQUIPMENT to be worn by a PATIENT [a clinical OPERATOR only views the display while he is physically with the PATIENT (e.g., viewing distance from < 1 m].

These requirements have changed because earlier editions of both standards for ELECTROCARDIOGRAPHIC MONITORING EQUIPMENT treated the requirements for GAIN, sweep speed and waveform aspect ratio equally. The ECG waveform's aspect ratio is the most clinically important of the three. In this edition of IEC 60601-2-27, requirements and tests related to waveform presentation were updated to account for the importance of aspect ratio, thereby addressing these market changes.

The revised sweep speed accuracy test of 201.12.1.101.7 verifies that the sweep speed of the ME EQUIPMENT is suitable for any NON-PERMANENT DISPLAY. The vertical conversion factor identified in that clause is used to determine whether the GAIN and aspect ratio of the ME EQUIPMENT are clinically acceptable.

Note that the Working Group felt that disclosure of the waveform height on the original display was not necessary, because another subclause requires a GAIN INDICATOR (see 201.12.1.101.9). This standard requires devices to provide a GAIN setting of 10 mm/mV. The accuracy of that setting is easily determined because the waveform GAIN is linearly proportional depending upon the vertical conversion factor determined in 201.12.1.101.7 that is applied.

Subclause 201.12.1.101.2 – Input dynamic range and differential offset voltage

ME EQUIPMENT must function properly in the presence of skin-to-electrode voltages that are known to be present.

Subclause 201.12.1.101.3 – Input impedance

This test assures an input impedance of at least 2.5 MΩ. This is necessary in order to avoid excessive loss of signal amplitude due to high skin impedances.

Subclause 201.12.1.101.8 – Frequency and impulse response

Most new ME EQUIPMENT uses digital signal processing which may make it difficult to determine the high frequency response using analogue sinusoidal signals. The sampling frequency chosen, based upon circuit design considerations, may be too low for accurate reproduction of sine wave signals. For this reason, ME EQUIPMENT has to comply with both methods A and B.

An isosceles triangular waveform simulates an ECG signal more closely than a sine wave. The high frequency response of the ME EQUIPMENT is reasonably determined by a single pole low pass filter. The loss of amplitude of the isosceles triangular waveform when using a low pass filter can be shown to be $20/Wf_c$ or $50T_R/W$ where W is the base width of the triangle, f_c is the corner frequency and T_R is the rise time of the low pass filter.

A loss in amplitude of 25 % corresponds to a high frequency response of 40 Hz when the base width of the triangular input is 20 ms. The high-frequency response limit of 40 Hz is based on two considerations. First, the primary purpose for monitoring ECG, heart rate determination, is adequately accomplished without a higher frequency response. Second, the persistent problem of high-frequency NOISE from power line frequencies and from muscle artifact is reduced by a 40 Hz bandwidth.

The low frequency response was previously stated in terms of a low cut-off frequency of 0.05 Hz, which was sufficient to achieve accurate ST-segment reproduction even for a first-order filter with unspecified phase response. More sophisticated filters are now commonly used which achieve equally accurate reproduction of ST-segment level and adequate slope reproduction, even though the filters have a higher cut-off frequency and thus enable faster baseline recovery. Hence, based on the AHA 1990 recommendations, low frequency response requirements are now stated in terms of impulse response requirements. The requirements specified in 201.12.1.101.8 are sufficient to ensure adequate ST-segment reproduction.

Subclause 201.12.1.101.10 – Common mode rejection

ME EQUIPMENT must reject some degree of the mains frequency voltages that capacitively couple to the PATIENT. The source capacitance of 200 pF that is achieved in the test, simulates the impedance of the PATIENT to earth.

In order to check the COMMON MODE REJECTION of the ME EQUIPMENT's circuit, it is necessary to disable any SUPPLY MAINS frequency notch filter. Otherwise, this test mostly checks the (differential mode) rejection of such a notch filter. It is desirable to achieve good COMMON MODE REJECTION at frequencies other than the SUPPLY MAINS frequency. Some modern ME EQUIPMENT has notch filters permanently on, i.e., they are not switchable (e.g., the line filter may always be on). Notwithstanding, the test of 201.12.1.101.10 must be done with all line filters disabled, even if it requires a special version of software and hardware to do so.

Subclause 201.12.1.101.12 – Pacemaker pulse display capability

The capability of displaying pacemaker pulses informs the clinical OPERATOR about the proper functioning of a pacemaker. Ideally, these pulses could be shown as a small spike or needle. In reality, the repolarization tail of a pacemaker pulse may fall within the same frequency band as QRS complex and may distort the ECG. A difference in baseline position prior to and after the pacemaker pulse keeps the distortion at a minimum.

Subclause 201.12.1.101.15 – Heart rate range, accuracy, and QRS detection range

The performance requirements for the heart rate meter in cases where the rate of the input signal is outside the measurement range stem from concerns about reported instances of falsely low readings in the presence of extremely high rates. Treatable tachycardias at rates up to 300/min occur in neonatal/pediatric and adolescent PATIENTS (Venugopalan[4)], et al., 2002). Such PATIENTS must be protected from falsely low heart rate readings and consequent failures to alarm.

Subclause 201.12.1.101.16 – Channel height and aspect ratio

ECG waveforms must be clearly visible from the disclosed intended viewing position. The usability process standards address this need even though this is not directly testable.

Channel height and waveform aspect ratio are fundamental characteristics of any visual presentation of an ECG waveform.

Earlier standards used the term “channel width” rather than “channel height”. While making technical changes related to the inadvertent linkage of the GAIN, sweep speed, and aspect ratio requirements in earlier standards, the committee chose to also correct this issue at the same time.

NOTE The original term “channel width” relates to how ECG waveforms are printed on strip recordings. If a strip recording is viewed while the ECG waveform is being printed, the amplitude of the QRS complex extends from left to right on the paper. Writers of earlier standards, therefore, used the term “channel width” to describe this. Considering instead how an ECG waveform appears on a screen, however, leads one to realize that “channel height” is more understandable.

The INTENDED USE/INTENDED PURPOSE of ELECTROCARDIOGRAPHIC MONITORING EQUIPMENT ultimately determines its channel height. For example, the INTENDED USE/INTENDED PURPOSE of wall-mounted ME EQUIPMENT and PATIENT-worn ME EQUIPMENT both require the ECG waveform to be clearly visible from the intended viewing position, but these products implement this requirement differently because their intended viewing positions are different.

– A channel height ≥ 30 mm for a wall-mounted monitor ensures the waveform is visible from 5 – 8 m.
– A channel height of 10 mm is sufficient for a PATIENT-worn monitor that presents 3 waveforms on a display that is 60 mm vertically (because the clinical OPERATOR views it from 1 – 2 m versus 8 m).

4) Venugopalan, P. et al. *Superventricular tachycardia in children: a report of three cases, diagnosis and current management*. Third GCC Conference of Faculties of Medicine on Medical Education, Sultan Qaboos University, Muscat, December 16-18, 2002.

Subclause 201.15.3.4.101 – ELECTRODES and PATIENT CABLES

Future development in ELECTRODES cannot be predicted but there is a possibility that they may contain a small amplifying device.

Subclause 202.6.2.6.1 bb) – Requirements

Due to the sensitivity of this type of ME EQUIPMENT it is not reasonable to expect the ME EQUIPMENT will be used in an environment where interference of such level will be induced.

Subclause 202.6.2.101 – Electrosurgery interference

There is no ideal test method to generate electrosurgical interference in a test laboratory but the one given in Figures 202.103 and 202.104 has been shown by experience to reproducibly give results similar to those seen in surgical practice. The test should be done in the normal working range of the HF SURGICAL EQUIPMENT (load approximately 500 Ω).

Disturbances caused by HF SURGICAL EQUIPMENT are considered NORMAL USE and consequently should not result in HAZARDS to the PATIENT. Therefore, after an appropriate recovery time the ME EQUIPMENT should resume normal operation without loss of stored data. Examples of typical stored data that may impact PATIENT safety are operating mode, ALARM SETTINGS (volume of auditory ALARM SIGNAL, ALARM LIMITS, ALARM OFF, etc.), and pacemaker pulse rejection if OPERATOR selectable. In contrast to these settings, the instantaneous heart rate or the displayed ECG waveform do not fall under stored data.

The most critical test is the application of a c ommon-mode HF voltage as shown in Figure 202.103. Capacitive coupling of HF to functional earth may cause the ME EQUIPMENT to fail to recover within the specified time if at all. For this reason it is not necessary to perform this test with a differential-mode HF voltage.

ECG telemetry systems are not used in operating theaters. Requiring protection against the effects of electrosurgery would unnecessarily burden such ME EQUIPMENT. Therefore, ECG telemetry systems are excluded from this test.

Subclause 208.6.1.2 – ALARM CONDITION priority

The intersection of the “Delayed” column and the “Minor injury or discomfort” row in Table 1 of IEC 60601-1-8:2006 contains “LOW PRIORITY or no ALARM SIGNAL”. Selection of “no ALARM SIGNAL” may be appropriate for these ALARM CONDITIONS in environments of use where a clinical OPERATOR continuously attends the PATIENT during NORMAL USE.

Such a selection is inappropriate for ME EQUIPMENT that is not continuously attended during NORMAL USE since failure to provide an auditory ALARM SIGNAL effectively means that the ALARM SYSTEM is disabled for those ALARM CONDITIONS.

Subclause 208.6.3.3.1 – Characteristics of auditory ALARM SIGNALS

An auditory ALARM SIGNAL that only occurs once (or does not occur, per Table 1 of IEC 60601-1-8:2006) may be appropriate for a LOW PRIORITY ALARM CONDITION in environments of use where the PATIENT is continuously attended by a clinical OPERATOR in NORMAL USE.

Such a selection is inappropriate for ME EQUIPMENT that is not continuously attended during NORMAL USE since not repeating the auditory ALARM SIGNALS means that the ALARM CONDITION is not likely to be recognized.

Subclause 208.6.3.3.2.101 – Volume of auditory ALARM SIGNALS reducible to zero

The primary alarm indicator that draws the attention to a clinical OPERATOR is the auditory ALARM SIGNAL – especially for ME EQUIPMENT that includes in its INTENDED USE/ INTENDED PURPOSE monitoring of PATIENTS that are not continuously attended by a clinical OPERATOR. Typical environments of use where PATIENTS are not continuously attended by health care professionals are intensive care units (ICU). Normally, a clinical OPERATOR is caring for several PATIENTS. Therefore, it is not possible to observe all PATIENT monitors at the same time to be aware of all visual ALARM SIGNALS that are not associated with auditory ALARM SIGNALS. In such an environment, reducing the volume of the auditory ALARM SIGNAL to zero means that the ALARM SYSTEM enters the inactivation state AUDIO OFF that must be indicated.

In such environments it is recommended to limit the adjustable volume of the auditory ALARM SIGNAL to a minimum sound pressure.

In a DISTRIBUTED ALARM SYSTEM where remote components of a DISTRIBUTED ALARM SYSTEM annunciate the ALARM SIGNALS the volume of the auditory ALARM SIGNAL may be reduced to zero (no sound pressure) depending on the use model (see second paragraph of rationale 208.6.4.2).

Subclause 208.6.4.2 – Delays to or from a DISTRIBUTED ALARM SYSTEM

Alarm generating ME EQUIPMENT annunciates ALARM SIGNALS in response to ALARM CONDITIONS that it detects. If this ME EQUIPMENT is part of a DISTRIBUTED ALARM SYSTEM, the DISTRIBUTED ALARM SYSTEM may annunciate the ALARM SIGNALS of that ALARM CONDITION at remote components of the DISTRIBUTED ALARM SYSTEM. It takes a finite amount of time for information related to an ALARM CONDITION to reach all components of a DISTRIBUTED ALARM SYSTEM. In many cases, this amount of time is very short, however, specific characteristics of a DISTRIBUTED ALARM SYSTEM can significantly delay annunciation of ALARM SIGNALS at remote components of the DISTRIBUTED ALARM SYSTEM.

Use models in intensive care units may require that remote equipment is operated as the primary alarming equipment (e.g. when the alarm generating ME EQUIPMENT is configured with the volume of its auditory ALARM SIGNAL reduced to zero – no sound pressure). In such an environment of use the overall delay time before remote components of a DISTRIBUTED ALARM SYSTEM annunciate ALARM SIGNALS should be limited to values that allow the clinician to respond to PHYSIOLOGICAL ALARM CONDITIONS (such as cardiac arrest, ventricular fibrillation, high systolic pressure, etc.) in time.

Inappropriate delay times for ALARM SIGNALS in a DISTRIBUTED ALARM SYSTEM may delay treatment of PATIENTS. Therefore, it is strongly recommended that RISK MANAGEMENT be applied to identify adequate “not to exceed” delay times of ALARM SIGNALS to remote components of a DISTRIBUTED ALARM SYSTEM.

Subclause 208.6.6.2.104 – TECHNICAL ALARM CONDITION indicating inoperable ME EQUIPMENT

ME EQUIPMENT that is inoperable should indicate this state on or adjacent to the display. This may be fulfilled by the absence of a visible trace.

Subclause 208.6.8.101 – TECHNICAL ALARM CONDITIONS

The alarm inactivation states ALARM OFF and ALARM PAUSED support the functionality that is essential for PATIENT monitoring equipment: in both alarm inactivation states (ALARM OFF and ALARM PAUSED), it is necessary for ELECTROCARDIOGRAPHIC MONITORING EQUIPMENT that visual

ALARM SIGNALS of TECHNICAL ALARMS CONDITIONS are displayed. The purpose of these visual ALARM SIGNALS is to inform the clinical OPERATOR – even during the alarm inactivation states ALARM OFF or ALARM PAUSED – that the ME EQUIPMENT (or a part of the ME EQUIPMENT) is not operating because a TECHNICAL ALARM CONDITION such as "ECG leads-off" interrupts the ECG monitoring of a PATIENT.

A TECHNICAL ALARM CONDITION may influence the validity of a measured value. For instance, the TECHNICAL ALARM CONDITION "ECG leads-off" prevents the heart rate from being calculated and displayed. Continuing to display the previously calculated heart rate may lead to misinterpretations by the clinical OPERATOR because this value is invalid during the TECHNICAL ALARM CONDITION. Appropriate means to indicate that the heart rate is invalid might be to display a blank heart rate value or a symbol where the heart rate is displayed.

In other cases, the tolerance of the measured values might be influenced or the measurement might be unreliable. In those cases, the clinical OPERATOR should be informed that the currently displayed value might be questionable. The displayed value should be marked accordingly.

Subclause 208.6.9 – ALARM RESET

The clinical OPERATOR action ALARM RESET performs the following actions: First, it stops the auditory ALARM SIGNAL. Second, it stops visual LATCHING ALARM SIGNALS of ALARM CONDITIONS that no longer exist. Third, it does not affect visual ALARM SIGNALS for ALARM CONDITIONS that continue to exist (those signals continue until the ALARM CONDITIONS ceases). Fourth, it enables the ALARM SYSTEM immediately to respond to a subsequent ALARM CONDITION. The fourth action "enabling the ALARM SYSTEM immediately" distinguishes the function ALARM RESET from the alarm inactivation states ALARM PAUSED, AUDIO PAUSED, ALARM OFF and AUDIO OFF.

In contrast to the alarm inactivation states ALARM PAUSED, AUDIO PAUSED, ALARM OFF and AUDIO OFF that temporarily or permanently disable the ALARM SYSTEM of ME EQUIPMENT, the function (clinical OPERATOR action) ALARM RESET maintains the ALARM SYSTEM in the "ON"-state but applies the functions that are specified in subclause 208.6.9 a) to e). This function stops the auditory ALARM SIGNALS, controls the visual ALARM SIGNALS depending on an existing or ceased ALARM CONDITION, and – as outlined before – keeps the ALARM SYSTEM enabled. As a result, the ALARM SYSTEM can respond immediately to a subsequent ALARM CONDITION without requiring additional clinical OPERATOR actions to activate the ALARM SYSTEM again. This also explains why AUDIO PAUSED is not the appropriate state because it does not allow the related control to perform these functions of ALARM RESET.

With the function ALARM RESET the clinical OPERATOR acknowledges an active ALARM CONDITION once and does not need to be concerned about activating the ALARM SYSTEM again because the ALARM SYSTEM remains in the "ON"-state. As a result, the function ALARM RESET avoids the possibility that the clinical OPERATOR might forget to activate the ALARM SYSTEM again.

Subclause 208.6.10 – NON-LATCHING and LATCHING ALARM SIGNALS

Different use models exist for ME EQUIPMENT that 1) is continually attended by a clinical OPERATOR (such as in operating theatres/rooms) and 2) is not continually attended by a clinical OPERATOR (such as in an ICU). In environments of use such as an ICU or emergency department, where PATIENTS are not continuously attended, a clinical OPERATOR normally cares for several PATIENTS.

Clinical OPERATORS who are caring for several PATIENTS cannot observe all of their PATIENTS at the same time. Clinical OPERATORS cannot easily identify short ALARM CONDITIONS that occur on

ME EQUIPMENT that provides NON-LATCHING ALARM SIGNALS or for mixes of NON-LATCHING and LATCHING ALARM SIGNALS. This inability to identify and quickly respond to important short ALARM CONDITIONS (e.g., short tachycardias) puts PATIENTS in HAZARDOUS SITUATIONS.

Configuring ME EQUIPMENT to only provide LATCHING ALARM SIGNALS forces clinical OPERATORS to respond to every ALARM CONDITION. While this is conceptually a good idea, frequent false ALARM CONDITIONS due to artifact or improperly set ALARM LIMITS can place a substantial administrative burden on the clinical OPERATOR.

LATCHING ALARM SIGNALS may be desirable within DISTRIBUTED ALARM SYSTEMS where remote equipment of an ME SYSTEM is not continuously attended by a clinical OPERATOR. NON-LATCHING ALARM SIGNALS may be desirable in an environment of use where the ME EQUIPMENT is continuously attended by a clinical OPERATOR.

Subclause 208.6.10.101 – NON-LATCHING ALARM SIGNALS for TECHNICAL ALARM CONDITIONS

A TECHNICAL ALARM CONDITION indicates that a physiological measurement is not ready or has been interrupted for technical reasons. Such technical interruptions of a measurement may be caused by an unintentional disconnection of a TRANSDUCER or a LEAD WIRE. For instance, the TECHNICAL ALARM CONDITION "ECG leads-off" prevents the heart rate from being calculated and displayed. This implies that the heart rate is not being monitored and as consequence potential ALARM CONDITIONS may not be indicated. Requiring NON-LATCHING ALARM SIGNALS for TECHNICAL ALARM CONDITIONS means those ALARM SIGNALS are displayed as long as the ALARM CONDITION exists and cease without clinical OPERATOR interaction when the TECHNICAL ALARM CONDITION is corrected.

Subclause 208.6.11.2.2 – Failure of remote communication of ALARM CONDITIONS

ME EQUIPMENT as part of a DISTRIBUTED ALARM SYSTEM is essential for reliable alarming in an unattended environment of use. For that reason ME EQUIPMENT that falls under the scope of this particular standard has to be so designed that it detects a communication failure and indicates the ALARM SIGNALS of the corresponding TECHNICAL ALARM CONDITION. Labeling of such an ME EQUIPMENT with a warning to the effect that it shall not be relied upon for receipt of ALARM SIGNALS is not appropriate to mitigate the RISK of critically ill PATIENTS they are exposed to.

The revised requirement 208.6.11.2.2 b) does only apply for ME EQUIPMENT that falls under the scope of this particular standard. The same applies of the entire content of this particular standard. Other components or parts of a DISTRIBUTED ALARM SYSTEM such as handheld devices, paging systems or even cellular phones do not fall under the scope of this particular standard; for those devices IEC 60601-1-8 applies.

Subclauses 208.6.11.101 – Inactivation/activation of ALARM SIGNALS at remote components of a DISTRIBUTED ALARM SYSTEM

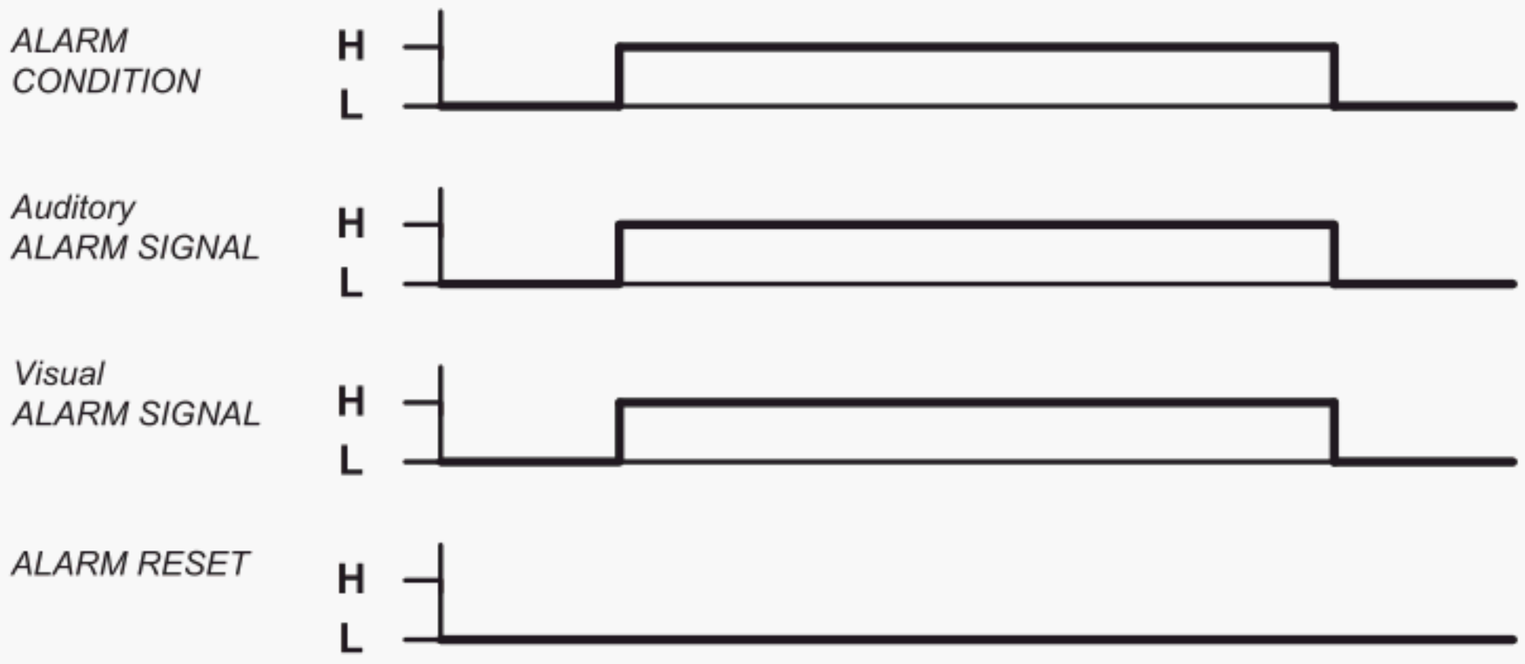
DISTRIBUTED ALARM SYSTEMS duplicate ALARM SIGNALS at remote components of a DISTRIBUTED ALARM SYSTEM such as a central station. Depending on the use model where the remote components of a DISTRIBUTED ALARM SYSTEM are being actively used it makes sense to activate/terminate the inactivation state ALARM PAUSED, AUDIO PAUSED, ALARM OFF or AUDIO OFF (depending on the configuration) and to activate ALARM RESET at remote components of a DISTRIBUTED ALARM SYSTEM. As indicated before, this remote control functionality depends on the use model in certain environments of use such as in intensive care units. For this reason, only the RESPONSIBLE ORGANIZATION should have access to the corresponding configuration. The configuration that enables the function of remote activation and termination of global inactivation

states (ALARM PAUSED, AUDIO PAUSED, ALARM OFF or AUDIO OFF) and remote activation of ALARM RESET must be protected. "Protected" means that the clinical OPERATOR of the ME EQUIPMENT must not have access in NORMAL USE to the selection of the capability to activate and terminate global inactivation states (ALARM PAUSED, AUDIO PAUSED, ALARM OFF or AUDIO OFF) and activation of ALARM RESET at remote components of a DISTRIBUTED ALARM SYSTEM. Adequate protection mechanisms are described in subclause 6.7 of IEC 60601-1-8:2006.

Annex BB
(informative)

Alarm diagrams of Clause 208/IEC 60601-1-8:2006

The following alarm status diagrams illustrate the auditory and visual ALARM SIGNALS for LATCHING and NON-LATCHING ALARM SIGNALS as defined in subclause 6.10 of IEC 60601-1-8:2006 and subclause 208.6.9 of this particular standard.



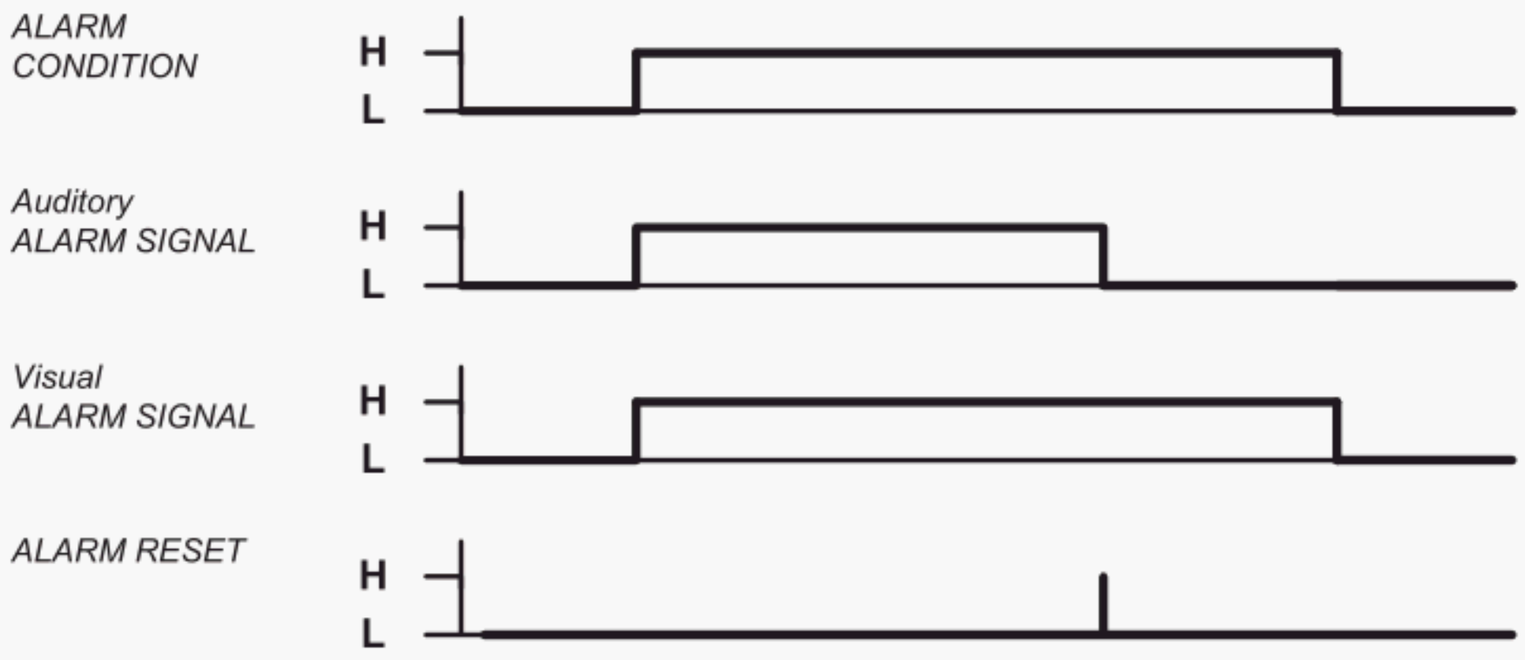
Key

H Activated state

L Deactivated state

Figure BB.101 – NON-LATCHING ALARM SIGNALS without ALARM RESET

Illustration of NON-LATCHING ALARM SIGNALS (Figure BB.101) as specified in IEC 60601-1-8 subclause 6.10: without OPERATOR interaction, the auditory and visual ALARM SIGNALS are indicated as long as the ALARM CONDITION exists. As soon as the ALARM CONDITION ceases, the auditory and visual ALARM SIGNALS are terminated automatically without any OPERATOR interaction.



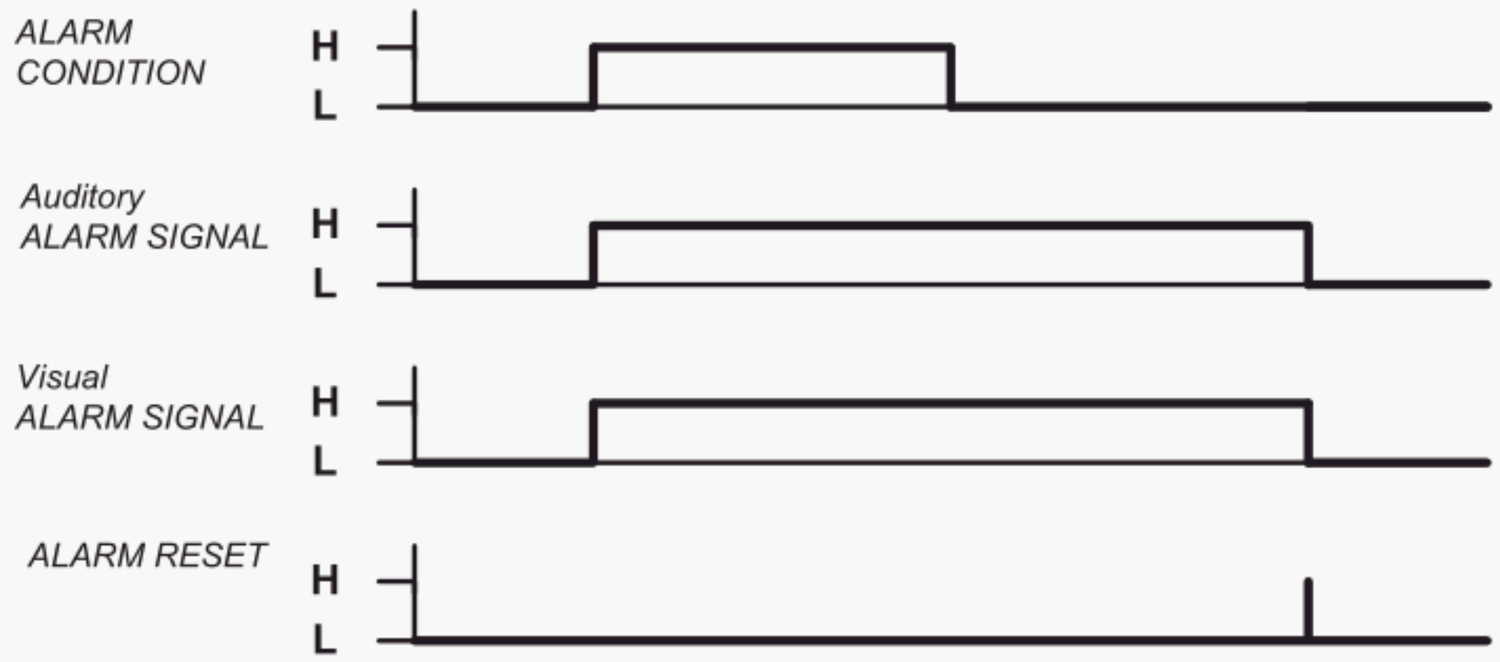
Key

H Activated state

L Deactivated state

Figure BB.102 – NON-LATCHING ALARM SIGNALS with ALARM RESET

Illustration of NON-LATCHING ALARM SIGNALS with ALARM RESET (Figure BB.102) as specified in IEC 60601-1-8, subclause 6.10 and in subclause 208.6.9 of this particular standard: Activating ALARM RESET stops the auditory ALARM SIGNAL. As soon as the ALARM CONDITION ceases the visual ALARM SIGNAL is terminated.



IEC 385/11

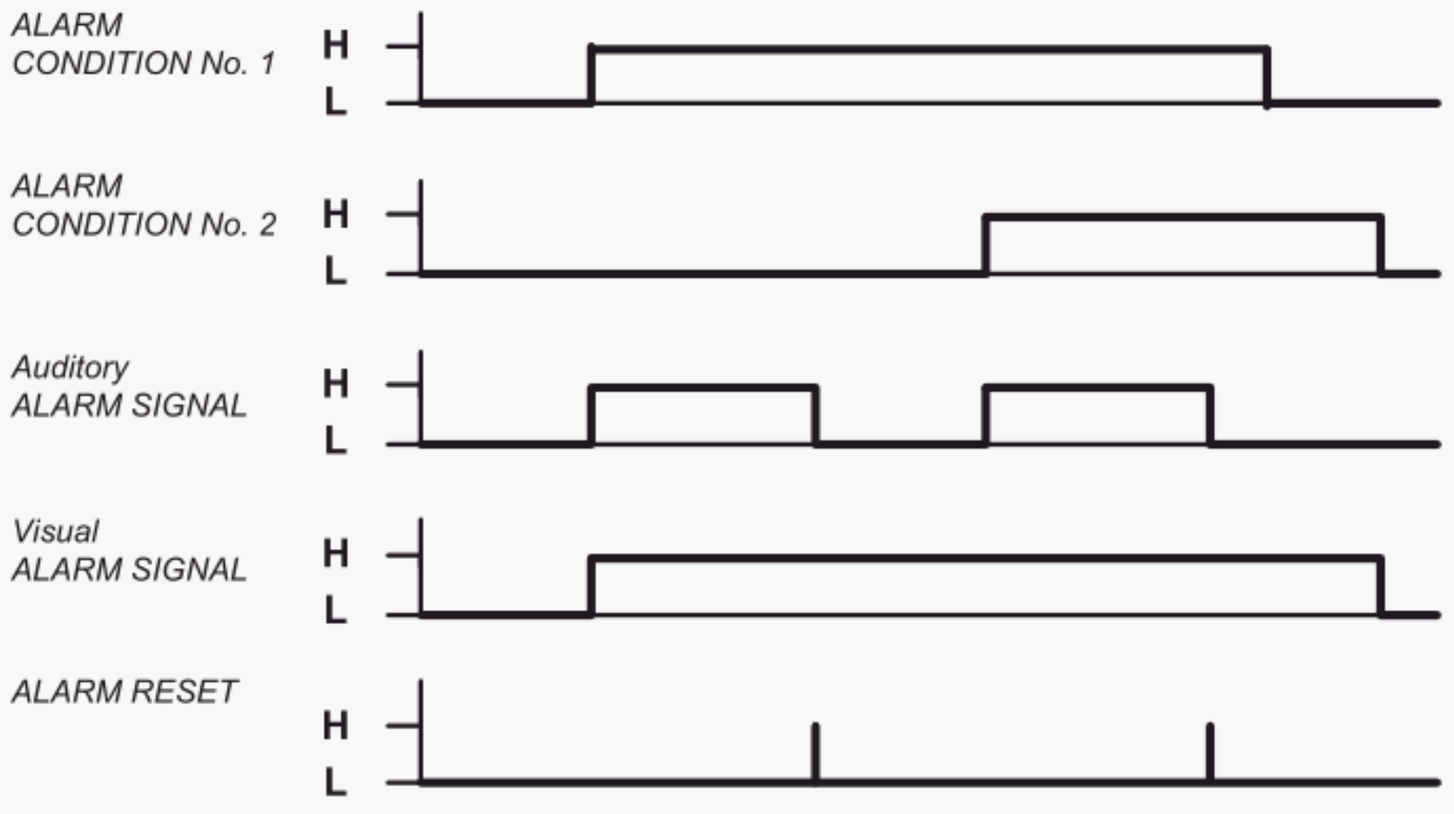
Key

H Activated state

L Deactivated state

Figure BB.103 – LATCHING ALARM SIGNALS with ALARM RESET

Illustration of LATCHING ALARM SIGNALS with ALARM RESET (Figure BB.103) as specified in IEC 60601-1-8, subclause 6.10, and in subclause 208.6.9 of this particular standard: without OPERATOR interaction, the auditory and visual ALARM SIGNALS are activated for an unlimited time. The OPERATOR is forced to reset ALARM SIGNALS of a PHYSIOLOGICAL ALARM CONDITION by activating the function ALARM RESET. After activating ALARM RESET the alarm behavior compares to NON-LATCHING ALARM SIGNALS.



IEC 386/11

Key

H Activated state

L Deactivated state

Figure BB.104 – Two ALARM CONDITIONS with ALARM RESET

Illustration of two ALARM CONDITIONS with ALARM RESET (Figure BB.104) as specified in IEC 60601-1-8 subclause 6.10 and in subclause 208.6.9 of this particular standard: a subsequent ALARM CONDITION of another physiological parameter reactivates the auditory ALARM SIGNAL.

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[1] ANSI/AAMI EC13:2002, *Cardiac monitors, heart rate meters, and alarms*

[2] PIPBERGER, HV. et al., Recommendations for standardization of leads and of specifications for instruments in electrocardiography and vectorcardiography. American Heart Association, *Report of the Committee on Electrocardiography, 1975, 52, p.11-31*.

Index of defined terms used in this particular standard

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5) IEC 61000-4-4:2004, *Electromagnetic compatibility (EMC) – Part 4-4: Testing and measurement techniques – Electrical fast transient/burst immunity test* (referenced in Clause 2 of IEC 60601-1-2:2007)

GAIN 201.3.204

GAIN INDICATOR 201.3.205

HIGH PRIORITY ..... IEC 60601-1-8:2006, 3.22

HF SURGICAL EQUIPMENT ..... IEC 60601-2-2:2009, 201.3.222

IMMUNITY ..... IEC 60601-1-2:2007, 3.13

IMMUNITY TEST LEVEL ..... IEC 60601-1-2:2007, 3.15

INFORMATION SIGNAL ..... IEC 60601-1-8:2006, 3.23

INTENDED USE/INTENDED PURPOSE ..... IEC 60601-1:2005, 3.44

INTERBURST INTERVAL ..... IEC 60601-1-8:2006, 3.25

INTERNAL ELECTRICAL POWER SOURCE ..... IEC 60601-1:2005, 3.45

INTERNALLY POWERED ..... IEC 60601-1:2005, 3.46

LATCHING ALARM SIGNAL ..... IEC 60601-1-8:2006, 3.26

LEAD 201.3.206

LEAD SELECTOR 201.3.207

LEAD WIRE 201.3.208

LEAKAGE CURRENT ..... IEC 60601-1:2005, 3.47

LIFE-SUPPORTING ME EQUIPMENT ..... IEC 60601-1-2:2007, 3.18

LOW PRIORITY ..... IEC 60601-1-8:2006, 3.27

MAINS VOLTAGE ..... IEC 60601-1:2005, 3.54

MANUFACTURER ..... IEC 60601-1:2005, 3.55

MEDICAL ELECTRICAL EQUIPMENT (ME EQUIPMENT) ..... IEC 60601-1:2005, 3.63

MEDICAL ELECTRICAL SYSTEM (ME SYSTEM) ..... IEC 60601-1:2005, 3.64

MEDIUM PRIORITY ..... IEC 60601-1-8:2006, 3.28

MULTIFUNCTION PATIENT MONITORING EQUIPMENT ..... IEC 60601-2-49:___[6)], 201.3.63

NEUTRAL ELECTRODE 201.3.209

NOISE 201.3.210

NON-LATCHING ALARM SIGNAL ..... IEC 60601-1-8:2006, 3.29

NON-PERMANENT DISPLAY 201.3.211

NORMAL USE ..... IEC 60601-1:2005, 3.71

OPERATOR ..... IEC 60601-1:2005, 3.73

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6) Second edition, to be published.

601227E

Erratum

American National Standard

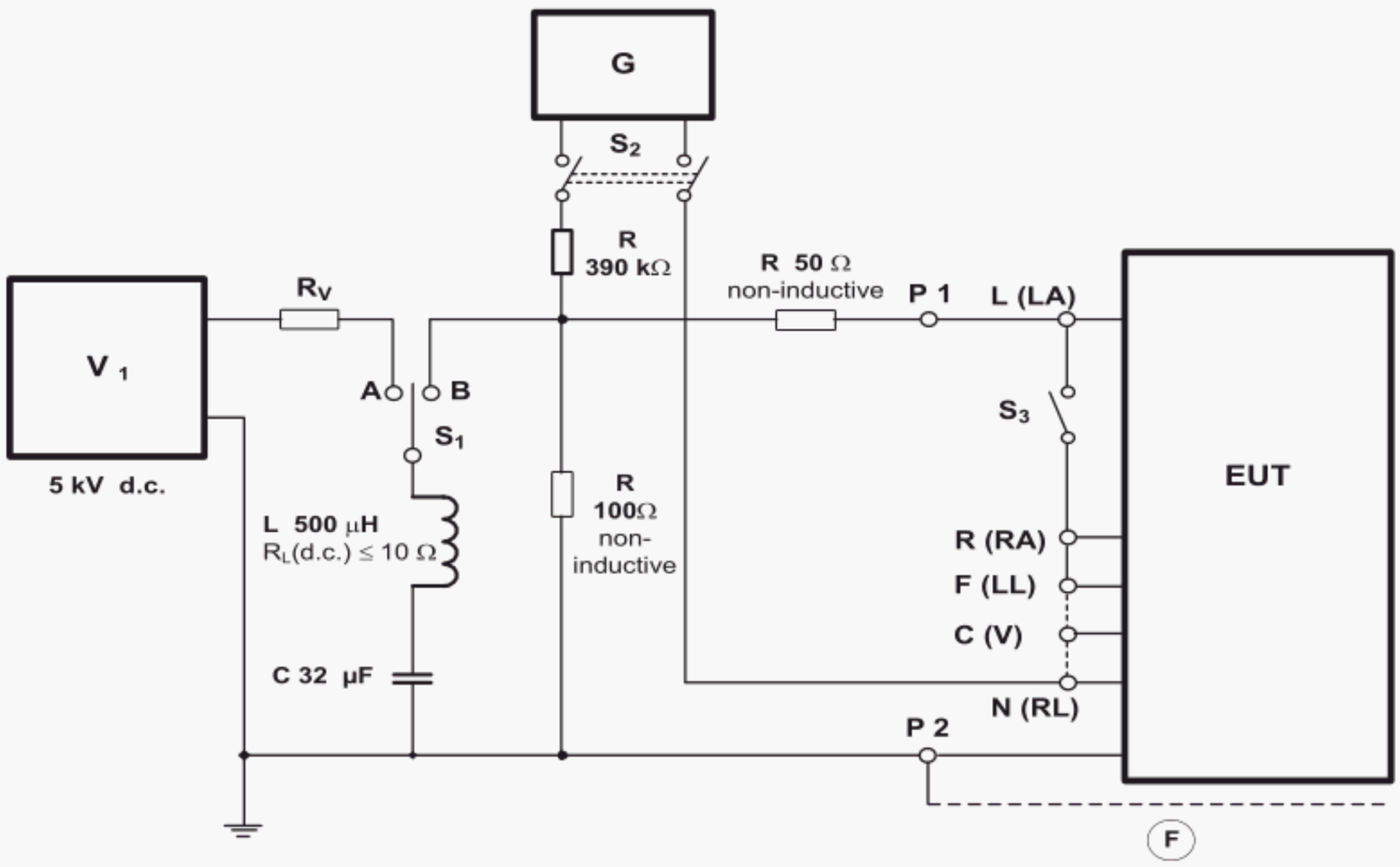
Medical electrical equipment – Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment

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

***Erratum* issued: 31 May 2012**

Page 16:

Replace Figure 201.103 by:



Components

G	Sine wave generator 20 V peak-to-valley of 10 Hz
V_1	High voltage source 5 kV d.c.
Ⓕ	Foil, simulating capacitance for CLASS II EQUIPMENT
S_1	Switch; max. load 60 A, 5 kV
S_2	Switch connecting the signal source, 5 kV
S_3	Switch applying the signal source to LEAD WIRES
R_L	d.c. resistance of inductance L
R_V	Current limiting resistor
P1	Connecting point for EUT (includes PATIENT CABLES)
P2	Connecting point for FUNCTIONAL EARTH TERMINAL and/or metal foil in contact with ENCLOSURE

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

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

This errata sheet is identical to CORRIGENDUM 1, issued May 2012, to IEC 60601-2-27 (Third edition – 2011)

Page 21:

In Figure 201.105 General Test Ciruit:

Delete the “***F***” between the lower part of the schematic and the legend starting with components.

Page 34:

201.12.1.101.15 * Heart rate range, accuracy, and QRS detection range

Replace last sentence 2nd paragraph by:

ECG input signals at rates above the upper limit of the specified display range, up to 300 1/min for adults and 350 1/min for neonatal and paediatric use shall not detect heart rates lower than the specified upper limits.