

American National Standard



ANSI/AAMI/ IEC 60601- 2-4:2010/ A1:2018

(Consolidated Text)

Medical electrical
equipment—Part 2-4:
Particular requirements for
the basic safety and
essential performance
of cardiac defibrillators,
including Amendment 1

Medical electrical equipment—Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators, including Amendment 1

Approved 21 November 2018 by
AAMI

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American National Standards Institute, Inc.

Abstract: This consolidated version includes the amendment which updates references and clarifies the scope as well as provides additional information for AEDs, defibrillator electrodes, audible warnings and cables.

Keywords: cardiac defibrillators, automated external defibrillators, defibrillator electrodes

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Committee representation

Association for the Advancement of Medical Instrumentation Defibrillator Committee

The adoption of IEC 60601-2-4:2010/A1 as an amendment to an existing national standard, ANSI/AAM/IEC 60601-2-4:2010, was initiated by the AAMI Defibrillator 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 Defibrillator Committee** had the following members:

Cochair: Oscar Tovar-Calderon, MD

Members: Regis DeSilva, MD, American College of Surgeons
Ram Dhurjaty
Nicole Hurley, PhD, WL Gore & Associates
Janice Jenkins, PhD, University of Michigan School of Dentistry
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Loriano Galeotti, PhD, FDA/CDRH
Don Lin, PhD
Nancy Moreyra, Philips
Bob Zito, Stryker Instruments

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 60601-2-4:2010/A1:2018

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

U.S. participation in IEC/SC 62D is organized through the U.S. Technical Advisory Group (TAG) for IEC/SC 62D, administered by 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 of the Amendment to IEC 60601-2-4, the AAMI DF, Defibrillator Committee decided to adopt it verbatim. This consolidated version contains the Amendment as well as the 2010 standard which has already been adopted by AAMI.

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.

NOTE Users of this standard are advised that this document is an AAMI identical adoption of an IEC document and that the following international conventions have been carried over to the AAMI publication:

- British English spelling (e.g. colour instead of color)
- Use of SI units (e.g. metres instead of feet, Celsius instead of Fahrenheit, etc.)
- Decimal comma instead of a decimal point (e.g. 1 000,15 instead of 1,000.15)

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, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

NOTE-This background does not contain provisions of the American National Standard, *Medical electrical equipment – Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators*, (ANSI/AAMI/IEC 60601-2-4), but it does provide important information about the development and intended use of the document.

NOTE-Beginning with the foreword on page vii, this American National Standard is identical to IEC 60601-2-4, A1.

Foreword

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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DISCLAIMER

This Consolidated version is not an official IEC Standard and has been prepared for user convenience. Only the current versions of the standard and its amendment(s) are to be considered the official documents.

This Consolidated version of IEC 60601-2-4 bears the edition number 3.1. It consists of the third edition (2010-12) [documents 62D/857/FDIS and 62D/878/RVD] and its amendment 1 (2018-02) [documents 62D/1549/FDIS and 62D/1555/RVD]. The technical content is identical to the base edition and its amendment.

This Final version does not show where the technical content is modified by amendment 1. A separate Redline version with all changes highlighted is available in this publication.

International standard IEC 60601-2-4 has been prepared by IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition constitutes a technical revision, revised to structurally align it with IEC 60601-1:2005 and to implement the decision of IEC SC 62A that the clause numbering structure of particular standards written to IEC 60601-1:2005 would adhere to the form specified in ISO/IEC Directives, Part 2:2004. 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 principle technical changes are as follows:

- 201.8.8.3, test 4: added additional test options;
- Figure 201.105: provided example of stainless steel plates. Added note for 10 Hz generator or shockable rhythm generator;
- Figure 201.101: Changed orientation of the lower diode at the oscilloscope connection;
- 202.6.1, .2, .4: "Additions" and "Replacements" corrected to be as originally intended;
- 201.101.1: Clarified preconditioning of a non-rechargeable battery;
- 201.3.207: Clarified definition of DUMMY COMPONENT;
- 201.15.4.101: In paragraph b), added reduced flex requirements for sterilizable internal paddles with specified limit on sterilization cycles;
- 201.15.4.3.103: Added an option for devices having non-changeable pre-programmed energy-setting sequences;
- 201.102.3.1, 2: Changed from specified defibrillation cycles to use of pre-programmed defibrillation sequence;
- 202.6.2.2.1: Changed ESD discharge sequence to match IEC 60601-1-2, third edition.

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

In this standard, the following print types are used:

- Requirements and definitions: roman type.
- *Test specifications: italic type.*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

- “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

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

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

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

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

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

The committee has decided that the contents of the base publication and its amendment 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.

Medical electrical equipment—Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators, including Amendment 1

201.1 Scope, object and related standards

Clause 1 of the general standard¹ applies, except as follows:

201.1.1 * Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of CARDIAC DEFIBRILLATORS, hereafter referred to as ME EQUIPMENT.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the general standard.

This particular standard does not apply to implantable DEFIBRILLATORS, remote control DEFIBRILLATORS, or separate stand-alone cardiac monitors (which are standardized by IEC 60601-2-27:2011 [2]²). Cardiac monitors which use separate ECG monitoring electrodes are not within the scope of this standard unless they are used as the sole basis for AED rhythm recognition detection or beat detection for synchronized cardioversion. DEFIBRILLATOR electrodes as described in 201.108 can also be used for ECG monitoring; however, due to the larger electrode area, the requirements of IEC 60601-2-27 are not applicable for DEFIBRILLATOR ELECTRODES.

Defibrillation waveform technology is evolving rapidly. Published studies indicate that the effectiveness of waveforms varies. The choice of a particular waveform including waveshape, delivered energy, efficacy, and safety has been specifically excluded from the scope of this standard.

However, due to the critical importance of the therapeutic waveform, comments have been added to the rationale which addresses considerations in waveform selection.

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

² Numbers in square brackets refer to the bibliography.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for cardiac defibrillators as defined in 201.3.202.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-2 applies as modified in Clause 202. 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

NOTE Informative references are listed in the bibliography beginning on page 73.

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

Amendment:

IEC 60601-1-2: 2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests*

Addition:

IEC 61000-4-2, *Electromagnetic compatibility (EMC) – Part 4-2: Testing and measurement techniques – Electrostatic discharge immunity test*

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

IEC 60601-1:2005/AMD1:2012

ISO 15223-1: 2016, *Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 apply, except as follows:

Addition:

NOTE An index of defined terms is found beginning on page 74.

201.3.201

AUTOMATED EXTERNAL DEFIBRILLATOR

AED

DEFIBRILLATOR that, once activated by the OPERATOR, analyses the ECG obtained from electrodes placed on the patient's skin identifies shockable cardiac rhythms, and automatically operates the DEFIBRILLATOR when a shockable rhythm is detected, hereinafter referred to as an AED

NOTE AEDs may provide varying levels of automation and be referred to by various terms. A semi-automatic DEFIBRILLATOR requires manual shock activation. A fully automatic DEFIBRILLATOR will provide shock without OPERATOR intervention.

201.3.202

CARDIAC DEFIBRILLATOR

MEDICAL ELECTRICAL EQUIPMENT intended to normalize the rhythm of the heart by an electrical pulse via electrodes applied either to the PATIENT's skin with external electrodes or to the exposed heart with internal electrodes

NOTE 1 A CARDIAC DEFIBRILLATOR can be referred to in this standard as a DEFIBRILLATOR or as ME EQUIPMENT.

NOTE 2 Such ME EQUIPMENT may also include other monitoring or therapeutic functions (e.g. transcutaneous pacing).

201.3.203

CHARGING CIRCUIT

circuit within the DEFIBRILLATOR intended for charging the ENERGY STORAGE DEVICE. This circuit includes all parts conductively connected to the ENERGY STORAGE DEVICE during the charging period

NOTE The CHARGING CIRCUITS for defibrillation and pacing functions may be separate or combined.

201.3.204

DEFIBRILLATOR ELECTRODE

electrode intended to deliver an electrical pulse for the purpose of cardiac defibrillation and which may also be used to provide transcutaneous pacing and other monitoring functions

NOTE DEFIBRILLATOR ELECTRODES may be internal or external and disposable or reusable.

201.3.205

DELIVERED ENERGY

energy which is delivered through the DEFIBRILLATOR ELECTRODES and dissipated in the PATIENT or in a resistance of specified value

201.3.206

DISCHARGE CIRCUIT

circuit within the DEFIBRILLATOR which connects the ENERGY STORAGE DEVICE to the DEFIBRILLATOR ELECTRODES. This circuit includes all switching connections between that device and the DEFIBRILLATOR ELECTRODES

NOTE The DISCHARGE CIRCUITS for defibrillation and pacing functions may be separate or combined.

201.3.207

DUMMY COMPONENT

test replacement for moulded components like transformers, resistors, semiconductors etc.

NOTE The DUMMY COMPONENT has a geometry equal to that of the component it will replace during the test, but provides dielectric isolation. The volume may lack parts of the original components (for example: semiconductor die, transformer cores and windings). The DUMMY COMPONENT makes it possible to test creepage, clearance and dielectric strength with the correct geometry without exceeding the internal maximum voltage of the part being replaced. The DUMMY COMPONENT shall be identical to the component replaced with respect to conductive external details such as metal legs, pins etc.

201.3.208

DEFIBRILLATOR TESTER

instrument capable of measuring the energy output from a CARDIAC DEFIBRILLATOR while generating a simulated ECG output to the CARDIAC DEFIBRILLATOR

201.3.209

ENERGY STORAGE DEVICE

component that is charged with the energy necessary to deliver an electrical defibrillation pulse to the PATIENT

NOTE The energy storage devices for defibrillation and pacing functions may be separate or combined.

201.3.210

FREQUENT USE

term used to describe a DEFIBRILLATOR designed to endure more than 2 500 discharges (see 201.103)

201.3.211**INFREQUENT USE**

term used to describe a DEFIBRILLATOR designed to endure less than 2 500 discharges (see 201.103)

201.3.212**INTERNAL DISCHARGE CIRCUIT**

circuit within the DEFIBRILLATOR which discharges the ENERGY STORAGE DEVICE without energizing the DEFIBRILLATOR ELECTRODES

201.3.213**MANUAL DEFIBRILLATOR**

DEFIBRILLATOR capable of being manually operated by the OPERATOR for selection of energy, charging and discharging

201.3.214**MONITOR**

part of a DEFIBRILLATOR providing a visual display of the electrical activity of the PATIENT's heart

NOTE The term is used within this particular standard to distinguish such a MONITOR from one which forms a separate ME EQUIPMENT in its own right even in cases where the separate stand-alone monitor is able to provide synchronization signals to the DEFIBRILLATOR, used as basis for AED rhythm recognition detection or providing control signals to the DEFIBRILLATOR.

201.3.215**RHYTHM RECOGNITION DETECTOR****RRD**

a system that analyzes the ECG and identifies whether a cardiac rhythm is shockable

NOTE The algorithm in an AED is designed for sensitivity and specificity for the detection of arrhythmias for which a defibrillation shock is clinically indicated. May be referred to as RRD.

201.3.216**SELECTED ENERGY**

energy which the defibrillator is intended to deliver, as determined by the setting of a manual control or by an automatic protocol

201.3.217**SEPARATE MONITORING ELECTRODE**

electrode applied to the PATIENT for the purpose of monitoring the PATIENT

NOTE These electrodes are not used to apply defibrillation pulses to the PATIENT.

201.3.218**STAND-BY**

mode of operation in which the ME EQUIPMENT is operational except that the ENERGY STORAGE DEVICE is not yet charged

201.3.219**STORED ENERGY**

energy which is stored in the DEFIBRILLATOR ENERGY STORAGE DEVICE

201.3.220**SYNCHRONIZER**

device allowing the DEFIBRILLATOR discharge to be synchronized with a specific phase of the cardiac cycle

201.3.221

PACER

EXTERNAL TRANSCUTANEOUS PACEMAKER

optional circuit within the DEFIBRILLATOR intended to stimulate the heart by a series of electrical pulses via electrodes applied to the PATIENT's skin

201.4 General requirements

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

201.4.2 RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS

Addition:

201.4.2.101 * Additional RISK MANAGEMENT requirements

MANUFACTURER shall address readiness for use in the RISK MANAGEMENT FILE.

Check compliance by inspection of RISK MANAGEMENT FILE.

201.4.3 ESSENTIAL PERFORMANCE

Addition:

201.4.3.101 * Additional ESSENTIAL PERFORMANCE requirements

Each of the three capabilities listed in Table 201.101, when included in a defibrillator, will be considered ESSENTIAL PERFORMANCE.

Where engineering judgement by the MANUFACTURER specifies performance in excess of ESSENTIAL PERFORMANCE, that performance may be degraded by external factors such as EMC, as long as the RISK MANAGEMENT FILE documents that ESSENTIAL PERFORMANCE is met.

Table 201.101 – Distributed ESSENTIAL PERFORMANCE requirements

Requirement	
Description	(Sub)clause
Deliver defibrillation therapy	201.12.1
Deliver synchronized defibrillation therapy	201.104
Accurately differentiate between shockable and nonshockable rhythms	201.107

201.5 General requirements for testing of ME EQUIPMENT

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

201.5.3 * Ambient temperature, humidity, atmospheric pressure

Addition:

- aa) The test required in 201.102.2 and 201.102.3 shall be performed at an ambient temperature of $0^{\circ}\text{C} \pm 2^{\circ}\text{C}$.

201.5.4 Other conditions

Addition:

- aa) Unless otherwise specified in this standard, all tests apply to all kinds of DEFIBRILLATOR types (manual, AEDs, INFREQUENT USE and FREQUENT USE DEFIBRILLATORS).

201.5.8 Sequence of tests

Addition:

The endurance test required in Clause 201.103 shall be performed after the test for excessive temperatures (see B.19 of the general standard).

The tests required in Clauses 201.101, 201.102, 201.104, 201.105 and 201.106 shall be performed after test B.35 of the general standard.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

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

201.6.2 * Protection against electric shock

Amendment:

Delete TYPE B APPLIED PART.

201.7 ME EQUIPMENT identification, marking and documents

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

201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

201.7.2.7 * Electrical input power from the SUPPLY MAINS

Replacement of paragraph beginning "If the rating of ME EQUIPMENT includes ...":

The RATED power input of mains operated ME EQUIPMENT shall be the maximum value attained by averaging the power input over any period of 2 s.

Additional subclauses:

201.7.2.101 * Concise operating instructions

Instructions for defibrillating, and where relevant, monitoring a PATIENT'S ECG, shall be provided by means of either clearly legible markings, or clearly understandable auditory commands.

Check compliance of auditory commands by the following test:

Auditory commands shall be clearly understandable to a person of normal hearing from a distance of 1 m in an ambient white noise (defined as flat ± 10 % over the range 100 Hz to 10 kHz) level of 65 dB, as measured with a Type 2 A-weighted sound level meter (see IEC 61672-1).

201.7.2.102 * INTERNALLY POWERED ME EQUIPMENT

INTERNALLY POWERED ME EQUIPMENT and any separate battery charger shall be marked with brief instructions for, as appropriate, the re-charging or replacement of the battery.

If a connection to the SUPPLY MAINS or to a separate battery charger is provided, the ME EQUIPMENT shall be marked to indicate any limitations of operation when the ME EQUIPMENT is connected to the SUPPLY MAINS or to the battery charger. Such marking shall include a description of the function as well as any limitations of operation of the ME EQUIPMENT with a discharged or missing battery.

201.7.2.103 Disposable defibrillator electrodes

The labelling accompanying the electrode package shall include, at a minimum, the following information:

- a) symbols (in accordance with ISO 15223-1: 2016) or a statement indicating the date the electrodes will expire (e.g., "use before ____") and the lot number or the date of manufacture;
- b) appropriate cautions and warnings, including limits on duration of electrode application and a caution that the unit package shall not be opened until immediately prior to use, if applicable;
- c) appropriate instructions for use, including procedures for skin preparation;
- d) instructions describing storage requirements, if applicable.

201.7.4 Marking of controls and instruments

Additional subclause:

201.7.4.101 * Selected energy control

The DEFIBRILLATOR shall be provided with a means for choosing the SELECTED ENERGY, unless the ME EQUIPMENT provides an automatic protocol for choosing the SELECTED ENERGY.

If the DEFIBRILLATOR is provided with means for the selection, continuously or in steps, of the SELECTED ENERGY then an indication of the SELECTED ENERGY in joules shall be incorporated, expressed as the nominal DELIVERED ENERGY in joules to a resistive load of 50 Ω .

Alternatively, the DEFIBRILLATOR may deliver a single preset energy, or a sequence of energies according to a preset protocol described in the instructions for use. If the DEFIBRILLATOR is designed to supply a single energy, or a programmed sequence of energies, no indication of the SELECTED ENERGY is required.

Check compliance by inspection.

201.7.9.2 Instructions for use

201.7.9.2.4 * Electrical power source

Replacement:

For mains-operated ME EQUIPMENT with an additional power source not automatically maintained in a fully usable condition, the instructions for use shall include a warning statement referring to the necessity for periodic checking or replacement of such an additional power source.

If leakage from a battery would result in an unacceptable RISK, the instructions for use shall include a warning to remove the battery if the ME EQUIPMENT is not likely to be used for some time.

The instructions for use shall provide information on the number of maximum energy discharges (in the case of AEDs, the number of preprogrammed discharges) which are available from a new and fully charged battery at 20 °C ambient temperature.

If an INTERNAL ELECTRICAL POWER SOURCE is replaceable, the instructions for use shall state its specification, and include full details of the charging procedure.

* The instructions for use shall contain advice on the periodic replacement of any primary or rechargeable battery.

If loss of the power source would result in an unacceptable RISK, the instructions for use shall contain a warning that the ME EQUIPMENT must be connected to an appropriate power source.

EXAMPLE Internal or external battery, uninterruptible power supply (UPS) or other available energy source.

For ME EQUIPMENT that is also capable of connection to the SUPPLY MAINS or to a separate battery charger, the instructions for use shall contain information on any limitations of operation when such a connection is made. This information shall include the case of a discharged or missing battery.

Additional subclause:

201.7.9.2.101 * Supplementary instructions for use

The instructions for use shall additionally contain the following:

- a) * warning not to touch the PATIENT during defibrillation;
- b) * a description of the correct type and method of handling the DEFIBRILLATOR ELECTRODES in use as well as a prominent warning that DEFIBRILLATOR ELECTRODES shall be kept well clear of other electrodes or metal parts in contact with the PATIENT. The OPERATOR shall be advised that other ME EQUIPMENT which has no DEFIBRILLATION-PROOF applied parts shall be disconnected from the PATIENT during defibrillation;
- c) caution for the OPERATOR to avoid contact between parts of the PATIENT's body such as exposed skin of head or limbs, conductive fluids such as gel, blood or saline and metal objects such as a bed frame or a stretcher which may provide unwanted pathways for the defibrillating current;
- d) * any environmental limitations regarding storing the ME EQUIPMENT (e.g. in a car or an ambulance under severe climatic conditions) immediately prior to use;
- e) where means are provided for monitoring via SEPARATE MONITORING ELECTRODES, instructions for the placement of these electrodes;
- f) * a recommendation calling the OPERATOR'S attention to the need for periodic maintenance of the ME EQUIPMENT irrespective of usage, especially:
 - cleaning of any reusable DEFIBRILLATOR ELECTRODES and the insulating parts of the handles;
 - sterilization procedures for any reusable DEFIBRILLATOR ELECTRODES or handles, including recommended sterilization methods and maximum sterilization cycles, if applicable;
 - cleaning of any reusable monitoring electrodes;
 - inspection of the packaging of any disposable DEFIBRILLATOR ELECTRODES and any disposable monitoring electrodes to ensure integrity of any seals and validity of any expiry date;
 - inspection of cables and electrode handles for possible defects;
 - functional checks;
 - charging of the ENERGY STORAGE DEVICE, if it is of a type requiring periodic charging (e.g. electrolytic or polyvinylidene fluoride (PVDF) capacitors);
- g) * information on the time required for charging a fully discharged ENERGY STORAGE DEVICE, when the DEFIBRILLATOR is set to maximum energy,
 - 1) with RATED MAINS VOLTAGE and, for an INTERNALLY POWERED DEFIBRILLATOR, with a new fully charged battery;

- 2) with MAINS VOLTAGE of 90 % of the RATED value and for an INTERNALLY POWERED DEFIBRILLATOR after 15 maximum energy discharges taken from a new fully charged battery for FREQUENT USE DEFIBRILLATOR or 6 discharges for INFREQUENT USE DEFIBRILLATOR;
 - 3) as 2) but measured from initially switching power on to ready for discharge at maximum energy;
- h) for AEDs, information on the maximum time from the initiation of rhythm analysis with a clear ECG signal to readiness for discharge. The defibrillator will indicate if the ECG signal is not presently analyzable.
- 1) with RATED MAINS VOLTAGE and, for an INTERNALLY POWERED DEFIBRILLATOR, with a new fully charged battery;
 - 2) with MAINS VOLTAGE of 90 % of the RATED value and for AN INTERNALLY POWERED DEFIBRILLATOR after 15 maximum energy discharges taken from a new fully charged battery for a FREQUENT USE DEFIBRILLATOR or 6 discharges for an INFREQUENT USE DEFIBRILLATOR;
 - 3) as 2) but measured from initially switching power on to ready for discharge at maximum energy;
- i) * for AEDs, information on whether or not the defibrillator can automatically abort a charged and ready for shock condition as follows:
- the RHYTHM RECOGNITION DETECTOR has detected a shockable rhythm and the DEFIBRILLATOR is charged and ready to shock;
 - the RRD has continued analyzing ECG after the initial shockable rhythm detection and has then detected a non-shockable rhythm;
- j) a warning that use of a DEFIBRILLATOR in the presence of flammable agents or in an oxygen enriched atmosphere presents an explosion and fire HAZARD;
- k) for ME EQUIPMENT intended for INFREQUENT USE, the intent shall be clearly stated and the limitations of the ME EQUIPMENT shall be clearly defined. Recommended or required status tests or preventive maintenance shall also be stated;
- l) for ME EQUIPMENT that delivers energy according to a preset protocol, information regarding the automatic selection of DELIVERED ENERGY and the conditions for resetting of the protocol shall be described in the instructions for use. The instruction for use shall also contain information of how to change the protocol if applicable.

201.7.9.3 Technical description

Additional subclauses:

201.7.9.3.101 * ESSENTIAL PERFORMANCE data for defibrillation

The technical description shall additionally provide:

- a) graphical plots in terms of time and current or voltage of the waveforms of the delivered pulses when the DEFIBRILLATOR is connected in turn to resistive loads of 25 Ω , 50 Ω , 75 Ω , 100 Ω , 125 Ω 150 Ω and 175 Ω and set to its maximum output, or according to an automatic protocol for the SELECTED ENERGY if applicable;
- b) energy accuracy specifications for the DELIVERED ENERGY in a 50 Ω resistor;
- c) if the DEFIBRILLATOR has a mechanism to inhibit its output when the PATIENT impedance is outside certain limits, disclosure of those limits.

201.7.9.3.102 * ESSENTIAL PERFORMANCE data of any SYNCHRONIZER

The technical description shall additionally provide:

- a) the meaning of any displayed synchronization or marker pulse;
- b) the maximum time delay between the synchronization pulse and delivery of the energy, once the output has been activated, including details of how the time delay was measured; and
- c) a statement concerning any conditions which will de-select the synchronized mode.

201.7.9.3.103 * ESSENTIAL PERFORMANCE data of the RHYTHM RECOGNITION DETECTOR

The technical description shall additionally provide:

- a) ECG database test report, (see 201.107 for database requirements);

A test report describing the recording methods, rhythm source, rhythm selection criteria, and annotation methods and criteria shall be available. The results of detector performance shall be reported in terms of specificity, true predictive value, sensitivity, and false positive rates. See 201.107 for definitions.

The report shall clearly summarize the sensitivity for detecting VF, and the sensitivity for detecting ventricular tachycardia (VT) for those devices designed to treat VT. For those devices designed to treat certain types of VT a description of the requirements for indication of VT as a shockable rhythm shall be included. The positive predictive accuracy, the false positive rate and overall specificity of the device shall also be reported. Reporting the specificity of the device for each non-shockable rhythm group (i.e. normal sinus rhythm, supraventricular rhythms such as atrial fibrillation and atrial flutter, ventricular ectopy, idioventricular rhythms and asystole) is recommended but not required.

- b) if the detector initiates analysis of the rhythm either automatically or following manual initiation by the OPERATOR, this shall be described;
- c) if the DEFIBRILLATOR incorporates a system that detects and analyzes physiological information other than the ECG, in order to increase the sensitivity or specificity of the AED, the technical description shall explain the method of operation of this system and the criteria for recommending shock delivery.

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

Addition:

- aa) Any APPLIED PART consisting of SEPARATE MONITORING ELECTRODES for monitoring the ECG shall be a TYPE CF APPLIED PART.

201.8.5.3 * MAXIMUM MAINS VOLTAGE

Addition:

Where the MAXIMUM MAINS VOLTAGE has been assigned the value of 250 V, and the derivation of test voltage from the value of the MAXIMUM MAINS VOLTAGE includes a 110 % multiplier, that multiplier shall not apply.

201.8.5.5 DEFIBRILLATION-PROOF APPLIED PARTS

201.8.5.5.1 * Defibrillation protection

- Differential-mode test

Replacement of the third paragraph ("After the operation of S, the peak....") by the following:

After the operation of S, the peak voltage between the points Y_1 and Y_2 is measured. Each test is performed both with the ME EQUIPMENT energized and not energized in turn and is repeated with V_T reversed in each case.

Additional subclauses:

201.8.5.5.101 * Isolation of DEFIBRILLATOR ELECTRODES

Arrangements to isolate the DEFIBRILLATOR ELECTRODES from other parts shall be so designed that, during the discharge of the ENERGY STORAGE DEVICE, hazardous electrical energies are excluded from the following:

- a) the ENCLOSURE;
- b) all PATIENT CONNECTIONS belonging to other PATIENT circuits;
- c) any SIGNAL INPUT/OUTPUT PART;
- d) a metal foil on which the ME EQUIPMENT is placed and which has an area at least equal to that of the base of the ME EQUIPMENT (CLASS II ME EQUIPMENT or ME EQUIPMENT with an INTERNAL ELECTRICAL POWER SOURCE).

Check compliance by the following test:

The above requirement is met when, after a discharge of the DEFIBRILLATOR connected as shown in Figure 201.101, the peak voltage between the points Y_1 and Y_2 does not exceed 1 V. Transients might be imposed on the measurement during the energy discharge. These are to be excluded from the measurement. This voltage corresponds to a charge of 100 μC from the part under test.

In the case where an active signal output part would affect the measured voltage between Y_1 and Y_2 , the specific signal output port is excluded from the measurement. However, the ground reference of such a signal output port is to be measured.

In the case where the connection of the measurement circuit of Figure 201.101 to an input/output port would create a failure of the device to function properly, the specific input/output port is excluded from measurement. However, the ground reference of such an input/output signal shall be measured.

DEFIBRILLATORS requiring an impedance within a certain range to be present at the output of the DISCHARGE CIRCUIT are to be tested connected to a 50 Ω resistive load. In the case of DEFIBRILLATORS requiring the detection of a shockable ECG in order to deliver a shock, an ECG simulator incorporating a 50 Ω resistive load is to be used.

Measurements are to be done at the maximum energy level of the device.

CLASS I ME EQUIPMENT is tested while connected to the protective earth.

CLASS I ME EQUIPMENT which is capable of operation without a SUPPLY MAINS, e.g. having an internal battery, shall also be tested without the protective earth connection.

Any connection to a FUNCTIONAL EARTH TERMINAL is to be removed.

The test is repeated with the earth connection transferred to the other DEFIBRILLATOR ELECTRODE.

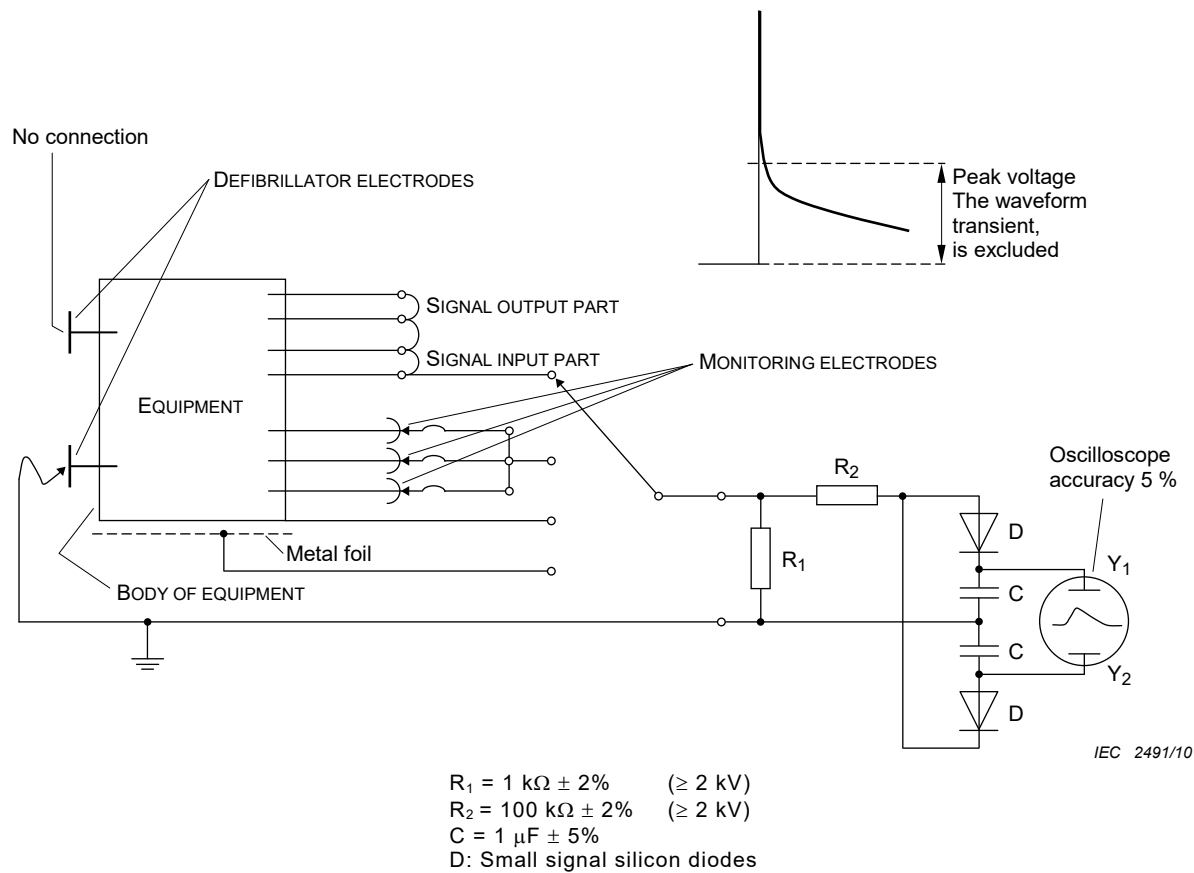


**Figure 201.101 – Dynamic test for limitation of energy
from different parts of the ME EQUIPMENT**
(see 201.8.5.5.101)

201.8.5.5.102 * APPLIED PARTS not being DEFIBRILLATOR ELECTRODES

Any APPLIED PARTS not being DEFIBRILLATOR ELECTRODES shall be DEFIBRILLATION-PROOF APPLIED PARTS unless the MANUFACTURER has taken steps to prevent their use at the same time as performing defibrillation with the same DEFIBRILLATOR.

201.8.5.5.103 Charging of the ENERGY STORAGE DEVICE

In keeping with subclause 201.13.1.3, unintentional charging of the ENERGY STORAGE DEVICE shall not occur when testing.

201.8.7 * LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

201.8.7.1 * General requirements

Replacement of b) dash 4 with:

- with ME EQUIPMENT energized in STAND-BY condition and fully operating and with any switch in the MAINS PART in any position;

For the measurement of PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT, the ME EQUIPMENT shall be operated in turn:

- 1) in STAND-BY;