List of Titles

American National Standard

ANSI/AAMI DF39:1993

Automatic external defibrillators and remote-control defibrillators

AAMI Association for the Advancement of Medical Instrumentation

List of Titles

Association for the Advancement of Medical Instrumentation
1110 N. Glebe Rd., Suite 220
Arlington, VA 22201-4795

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DF39 External Defibrillators and Remote-Control Defibrillators

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American National Standard

ANSI/AAMI DF39—1993

Automatic external defibrillators and remote-control defibrillators

Developed by
Association for the Advancement of Medical Instrumentation

Approved 16 September 1993 by
American National Standards Institute

Abstract:

Covers energy range, controls and indicators, and other features of automatic or semiautomatic external defibrillators, including those designed for inhospital use, for use in homes and other locations, and remote-control defibrillators. Also includes requirements for self-adhesive electrodes for monitoring and defibrillation and requirements applicable to optional capabilities such as external pacing.

Association for the Advancement of Medical Instrumentation

AAMI Defibrillator Committee

This standard was developed by the Defibrillator Committee of the Association for the Advancement of Medical Instrumentation. Committee approval of the standard does not necessarily imply that all committee members voted for its approval.

Cochairs: Francis Charbonnier, PhD
Richard S. Crampton, MD

Members: A. A. J. Adgey, MD, Royal Victoria Hospital
Laura Aguilar, 3M Company
John Anderson, Faculty of Ulster Polytechnical
Alan S. Berson, PhD, National Heart, Lung and Blood Institute
Francis Charbonnier, PhD, Hewlett-Packard Company
Barbara G. Cooper, ECRI
Richard S. Crampton, MD, University of Virginia (American College of Cardiology)
Stephen Daleo, PPG Biomedical Systems Division
Regis De Silva, MD, Harvard Medical School
Jerry L. Dysart, Kilovac Corporation
Joseph A. Gascho, MD, The M. S. Hershey Medical Center
L. A. Geddes, PhD, Purdue University
Laurence Gessman, MD, Deborah Heart and Lung Center
Lisbeth Isbrandt, S&W Medico Teknika A/S
Janice Lorraine Jones, PhD, Georgetown University
John L. Karpowicz, Laerdal Manufacturing Corporation
Richard Kerber, MD, University of Iowa, University Hospital
Glenn W. Krapf, Medphone Corp.

Vincent J. B. Pierdominici, Jr., FDA, Winchester Engineering and Analytical Center
Leon Resnekov, MD, University of Chicago Hospital and Clinic
Harry Robbins, Defense Personnel Support Center
David Schlageter, Marquette Electronics
William J. Smirles, R2 Systems
Michael Smith, General Devices
Greg Sorknes, SpaceLabs
Sidney Steinberg, PhD, Medphone Corporation
W. A. Tacker, Jr., MD, PhD, Purdue University
Kok-Swang Tan, PhD, Bureau of Radiological Medical Devices, Canada
W. D. Weaver, MD, University of Washington Hospital
Spencer Wende, Mennen Medical Inc.
Robert C. Wesley, Long Beach VA Medical Center
Michael Willingham, Physio Control Corp.
James D. Woodburn, MD, University Association of Emergency Medicine

Alternates:

David M. E. Allan, MD, R2 Systems
Robert Cangelosi, FDA Center for Devices and Radiological Health
D. Craig Edwards, First Medic
John Kuphal, Laerdal Manufacturing Co.
Martin Rockwell, Hewlett-Packard Company
S. Eric Wachtel, Medphone Corporation

NOTE—Participation by federal agency representatives in the development of this standard does not constitute endorsement by the federal government or any of its agencies.

Foreword

This standard was developed by the Defibrillator Committee of the Association for the Advancement of Medical Instrumentation (AAMI). The objective of the standard is to provide minimum labeling, performance, and safety requirements that will help establish a reasonable level of safety and efficacy in the use of automatic or semiautomatic external cardiac defibrillator devices.

The safety and performance criteria defined in this standard, and specifically the test methods prescribed, are intended for use in design qualification or "type" evaluation by device manufacturers, and may not all be appropriate for users. However, to ensure continuing safety and efficacy of devices in use, it is essential that users routinely inspect, test, and maintain every device according to the manufacturer's instructions, and rely on a biomedical engineering department or other qualified personnel to perform comprehensive performance tests and maintenance, again according to the manufacturer's instructions.

The standard does not guarantee a specific efficacy to terminate fibrillation but does impose requirements, e.g., on selectable energy, that are intended to provide reasonable assurance of successful defibrillation of patients in ventricular fibrillation (VF).

The standard primarily is written for defibrillator manufacturers, to give them clear labeling, design, performance, and test specifications that, if met, should promote patient and operator safety and a high level of efficacy. The standard also will be useful to defibrillator users because knowledge of the standard will give the user a more precise understanding of the characteristics and limitations of the defibrillator; such understanding is conducive to safer and more efficacious use of the device. To that end, the standard also contains brief recommendations and guidelines for optimum use of defibrillators.

This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. In addition, as other standards having application to cardiac defibrillators are promulgated, they may be incorporated by reference in order to provide additional assurance of safety and

efficacy. Such standards may address characteristics such as electromagnetic compatibility (EMC), performance under adverse environmental conditions, and the performance of electrocardiographic (ECG) monitors integral to defibrillators.

This standard reflects the conscientious efforts of concerned physicians, clinical engineers, manufacturers, and government representatives to develop a standard for those performance levels that can reasonably be achieved at this time.

As used within the context of this standard, "shall" indicates requirements strictly to be followed in order to conform to the standard; "should" indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action is depreciated but not prohibited; "may" is used to indicate that a course of action is permissible within the limits of the standard; and "can" is used as a statement of possibility and capability. "Must" is used only to describe "unavoidable" situations.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to AAMI, 3330 Washington Boulevard, Suite 400, Arlington, VA 22201-4598.

NOTE—This foreword is not a part of the American National Standard, *Automatic external defibrillators and remote-control defibrillators* (ANSI/AAMI DF39—1993).

Automatic external defibrillators and remote-control defibrillators

1 Scope

1.1 General

This standard covers minimum labeling, performance, and safety requirements for automatic or semi-automatic (advisory) external defibrillators (AED), remote-control defibrillators (RCD), and self-adhesive combination electrodes. An AED is an electronic apparatus that includes sensors and analysis algorithms capable of identifying ventricular fibrillation (VF) and other electrocardiographic (ECG) rhythms. The AED is connected to a patient and delivers a brief electrical shock to the heart if the device indicates VF or other arrhythmias for which a shock is appropriate. The defibrillator shock is delivered automatically by the device in the case of an automatic defibrillator, or is delivered by the operator (upon recommendation from the device) in the case of a semiautomatic or advisory defibrillator.

An RCD transmits an ECG by telephone to a medical response center and is remotely operated from that center.

Self-adhesive electrodes for monitoring and defibrillation, which are a necessary and important component of AEDs and RCDs, are also covered by this standard.

Algorithms for prompt and accurate identification of cardiac rhythms, particularly VF, are an essential requirement for the performance and safety of AEDs. Though it is difficult to develop a traditional standard for a VF detection algorithm, this standard defines minimum testing and reporting procedures for describing and verifying the performance of the arrhythmia detection component of the AED. Only ECG rhythm detectors are considered, as it is premature to specify and standardize requirements for other non-ECG rhythm detectors which may be developed and used in the future.

AEDs may be designed specifically for hospital use, for prehospital use by emergency response teams, or for use in homes or various locations (factories, airplanes, etc.). This standard recognizes and covers the differentiation of requirements for these various applications.

AEDs may also have additional optional functional capabilities. This standard covers the most important of these optional functions, i.e., external transcutaneous pacing.

A section containing referee test methods is included in this standard to define the methodology by which compliance with the requirements can be verified. These test methods are designed and intended for use primarily by manufacturers, though end users of the device may also find them useful.

1.2 Inclusions

This standard specifically addresses

a) AEDs, including algorithms for recognition of cardiac rhythms and particularly detection of VF;

b) RCDs, which communicate with and are controlled from a medical response center;

c) external transcutaneous pacers, when a part of a defibrillator-pacer instrument;

d) self-adhesive combination (defibrillation/monitoring) or universal function (defibrillation/monitoring/pacing) electrodes.

1.3 Exclusions

This standard does not cover

a) manual defibrillators that do not have a rhythm recognition algorithm or cannot be operated and controlled from a remote location. Manual defibrillators are covered by a separate standard, ANSI/AAMI DF2—1989;

b) AEDs or external pacers designed and indicated for use on infants or small pediatric patients (no such devices currently exist);

c) AEDs used for long-term ECG monitoring, either in or out of the hospital;

d) stand-alone cardiac monitors and arrhythmia analysis systems;

e) stand-alone pacemakers, implantable or external transcutaneous;

f) automatic implantable cardioverter-defibrillators or pacer-cardioverter-defibrillators (ICDs).

1.4 Abbreviations and acronyms

A, mA, µA,	Ampere, milliampere, microampere,
nA	nanoampere (units of electrical current)
AAMI	Association for the Advancement of Medical Instrumentation
AED	Automatic or advisory external defibrillator
ANSI	American National Standards Institute
CISPR	International Special Committee on Radio Interference
ECG	Electrocardiogram
E_{MAX}	Maximum delivered energy
EMC	Electromagnetic compatibility
F, µF, nF	Farad, microfarad, nanofarad (units of capacitance)
Hz, kHz,	Hertz, kilohertz, megahertz, gigahertz (units of

MHz, GHz	frequency)
IEC	International Electrotechnical Commission
ohm, kohm, Mohm	Ohm, kilohm, megohm (units of resistance)
RCD	Remote-control defibrillator
rf	Radio frequency
TTI	Patient transthoracic impedance
V, kV, mV	Volt, kilovolt, millivolt (units of voltage)
VF	Ventricular fibrillation
VT	Ventricular tachycardia

2 Normative references and definitions

2.1 Normative references

The following documents contain provisions which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to use the most recent editions of the documents indicated below.

2.1.1 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Cardiac defibrillator devices*. ANSI/AAMI DF2—1989. Arlington (Vir.): AAMI, 1989. American National Standard.

2.1.2 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Design, testing and reporting of performance results of automatic external defibrillators*. AAMI TIR2—1987. Arlington (Vir.): AAMI, 1987. Technical Information Report.

2.1.3 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Disposable ECG electrodes*. ANSI/AAMI EC12—1991. Arlington (Vir.): AAMI, 1991. American National Standard.

2.1.4 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Safe current limits for electromedical apparatus.* ANSI/AAMI ES1—1985. Arlington (Vir.): AAMI, 1985. American National Standard.

2.1.5 INTERNATIONAL ELECTROTECHNICAL COMMISSION (IEC). *Electromagnetic compatibility for industrial process measurement and control equipment*. (IEC 801 series). Geneva: IEC. (Available from ANSI.)

-801-1 (1984)	*General introduction*
-801-2 (1991)	*Electrostatic discharge requirements*
-801-3 (1992)	Currently document 65A(SEC)135, 77B(SEC)100, *Immunity to radiated radio frequency electromagnetic fields* (committee draft)
-801-4 (1988)	*Electrical fast transient burst requirements*
-801-5	Currently document 65A(SEC)137, *Voltage surge immunity requirements*
-801-6 (1992)	Currently document 65A(SEC)131, 77B(SEC)91, *Immunity to conducted disturbances induced by rf fields* (committee draft)

2.1.6 INTERNATIONAL ELECTROTECHNICAL COMMISSION (IEC). *Medical electrical equipment, Part 2: Collateral standard: Electromagnetic compatibility: Requirements and test*. (IEC 601-1-2). Geneva:

IEC, 1993. (Available from ANSI.)

2.1.7 INTERNATIONAL ELECTROTECHNICAL COMMISSION (IEC). *Medical electrical equipment, Part 2: Particular requirements for the safety of cardiac defibrillators and cardiac defibrillator/monitors*. (IEC 601-2-4). Geneva: IEC, 1983.

2.1.8 INTERNATIONAL SPECIAL COMMITTEE ON RADIO INTERFERENCE. *Limits and methods of measurement of electromagnetic disturbance characteristics of industrial, scientific and medical (ISM) radio frequency equipment*. (CISPR 11, 2nd edition). CISPR, 1990. (Available from ANSI.)

2.2 Definitions

For the purpose of this standard, the following definitions apply:

2.2.1 automatic external defibrillator (AED): A defibrillator that analyzes the cardiac rhythm, identifies shockable rhythms, and includes logic circuitry to automatically operate the defibrillator when a shockable rhythm (ventricular fibrillation [VF] and certain forms of ventricular tachycardia [VT]) are detected.

2.2.2 event documentation: A sufficiently detailed record of events and activities surrounding an episode of cardiac arrest and attempted defibrillation or pacing. The record, which includes ECG traces and may include voice recording, allows a retrospective analysis of the event for purposes of medical control, quality assurance, and further operator training.

2.2.3 external defibrillation: The application of a high-energy, short-duration electrical discharge to the heart (myocardium) by means of electrodes placed on the body surface at appropriate locations, in an attempt to terminate VF and restore an organized, perfusing cardiac rhythm.

2.2.4 external transcutaneous pacer: A device that may analyze the ECG and that delivers pacing pulses to the heart, at a controllable rate and current, by means of electrodes placed on the body surface.

2.2.5 pacing: The application of moderate-energy, very short-duration pulses to the heart, at a controlled current and frequency, to achieve cardiac contractions of appropriate strength and rate in case of complete AV block or extreme bradycardia. In transcutaneous external pacing, electrodes placed on the body surface are used to sense the cardiac rhythm and to deliver the pacing pulses.

2.2.6 remote-control defibrillator (RCD): A defibrillator that is connected by a communication link (usually a landline telephone) to a medical response center, and that is remotely controlled and operated from the response center. See section 3.5 for detailed definitions of RCDs and communication links.

2.2.7 rhythm recognition detector: An algorithm that analyzes the ECG and identifies the cardiac rhythm. The algorithm in an AED is designed for maximum sensitivity and specificity for the detection of VF.

2.2.8 secondary detector systems: Sensors for algorithms which may be used, in addition to ECG analysis, to increase the sensitivity and specificity of cardiac arrest detection by the AED. An example is the opharyngeal airway electrode which was used by Cardiac Resuscitator Corporation in the early 1980s to detect gag reflex and breathing.

2.2.9 self-adhesive combination defibrillator/monitoring electrodes: Self-adhesive electrodes placed on the chest to acquire an ECG and also to transmit the defibrillation discharge to the patient.

2.2.10 semi-automatic or advisory external defibrillator (AED): A defibrillator that analyzes the cardiac rhythm, identifies shockable rhythms, and then provides a visual or auditory message to advise the operator to defibrillate.

2.2.11 synchronized cardioversion: The timed application of a high-energy, short-duration electrical discharge to the heart to terminate arrhythmias which preserve ventricular contractions (such as VT or atrial fibrillation). R waves (associated with ventricular contractions) are detected and the electrical discharge is

timed to occur shortly after the R wave (to avoid the vulnerable period of the heart cycle).

2.2.12 universal function electrodes: Self-adhesive electrodes that are designed for acquisition of the ECG and for efficient transmission of both defibrillation and pacing pulses.

2.2.13 ventricular fibrillation: A chaotic cardiac rhythm in which the normal activation sequence of myocardial cell depolarization fails and individual cells depolarize rapidly and in a random pattern, resulting in abrupt loss of cardiac output. VF usually causes death after a few minutes. It is usually self-sustaining and can be terminated only by a strong electrical discharge (defibrillation).

3 Requirements

The rationale (annex A) provides background information that is helpful in understanding and interpreting the standard; therefore, careful study of the rationale is recommended.

3.1 Device labeling

Markings affixed to defibrillators shall resist the deleterious effects of handling and cleaning expected during intended use. Good contrast shall be maintained between the lettering and background materials.

3.1.1 Defibrillator

3.1.1.1 Identification

Identification and electrical rating markings shall be readily visible on the defibrillator and the battery charger.

3.1.1.1.1 Defibrillator labeling

Identification and electrical rating markings shall include, at a minimum:

a) name or trade name of the manufacturer;

b) catalog number or equivalent designation;

c) serial number or other unique product controlling identification traceable to the date of manufacture;

d) battery catalog number or equivalent designation;

e) identification of applicable battery charger from which the battery can be recharged; if the unit can be powered by the battery charger, an indication of any limitations of operation when the battery charger is connected to the line (mains) voltage and to the equipment.

3.1.1.1.2 Battery charger labeling

Identification and electrical rating markings shall include, at a minimum:

a) name or trade name of the manufacturer;

b) catalog number or equivalent designation;

c) serial number or other unique product controlling identification traceable to the date of manufacture, if applicable;

d) line (mains) voltage range;

e) line frequency range;

f) identification of applicable battery or unit with which the battery charger is used.

3.1.1.2 Defibrillator controls and indicators

The functions of controls and indicators shall be labeled according to the following:

a) The ON/OFF control shall be labeled with the ON and OFF positions clearly indicated. This may be accomplished by a switch, with two positions labeled ON and OFF; as part of the Energy Select control, with a distinct position labeled OFF; by an alternate action mechanism labeled ON/OFF, with a power ON indicator to distinguish the mode; or by other designs that clearly indicate the operating condition of the defibrillator.

NOTE—The OFF condition of the ON/OFF control may additionally be labeled DISARM.

b) The operating mode selection control that activates cardiac rhythm interpretation and defibrillator operation, if present, shall be appropriately labeled. The control that deactivates cardiac rhythm interpretation and defibrillator operation, if separately provided, shall be appropriately labeled. Indication of the operating mode selected (active analysis or idle) shall be clearly designated. Any additional mode selections, if provided, shall be designated by distinctively different titles which are unlikely to be confused with the two primary mode titles.

c) The control that selects the amount of delivered energy, if present, shall be labeled ENERGY SELECT.

d) Indication of energy selected shall be labeled SELECTED ENERGY, JOULES.

e) The control that activates the charge, if present, shall be labeled CHARGE.

f) The control for delivery of electrical energy through the patient circuit, if present, shall be labeled SHOCK. The time period during which this control is active shall be clearly indicated.

g) The control for internal dissipation of electrical energy, other than through the patient circuit, shall be labeled DISARM.

h) Actions required to operate the defibrillator shall be clearly labeled and shall be identified sequentially in clear, visible fashion.

3.1.1.3 Defibrillator caution and warning notices

The following notices shall be permanently attached to the defibrillator in a readily visible location:

a) "CAUTION—HAZARDOUS ELECTRICAL OUTPUT. This equipment is for use only by qualified personnel."

b) "CAUTION—ELECTRIC SHOCK HAZARD. Do not remove cover (or back). Refer servicing to qualified service personnel." This notice shall readily be visible during any approach to attempt servicing.

c) "DANGER—Possible explosion hazard if used in the presence of concentrated oxygen."

3.1.2 Self-adhesive electrodes for monitoring and defibrillation

In addition to the requirements of applicable federal regulations, the labeling for self-adhesive electrodes shall comply with the provisions of this section. The labeling accompanying the electrode package shall include, at a minimum, the following information:

a) a statement indicating the date beyond which conformance of the electrodes with the requirements of this standard cannot be assured (e.g., "use before_____") and the lot number, or a statement indicating the date of manufacture, shelf life, and lot number;

b) appropriate cautions and warnings, including limits on duration of electrode application and a caution that the unit package should not be opened until immediately prior to use, if applicable;

c) appropriate instructions for use, including procedures for skin preparation;

d) instructions concerning storage requirements, if applicable.

3.2 Operating instructions and maintenance manuals

An instruction manual shall be provided with each defibrillator. The instruction manual shall include, at a minimum:

a) specific operating instructions for the equipment, including the use and adjustment of all operator-accessible controls and indicators, interaction with other system components where applicable, and environmental limitations;

b) specification of accessory components required for system operation—such as electrodes, patient connection cables if detachable—battery, and battery charger;

c) specific instructions for the defibrillation procedures, including any predetermined operating mode sequences and energy level selections, safety considerations in the intended use, and cautions against misuse;

d) instructions on care, preventive maintenance, cleaning, daily check and testing, and periodic bench testing of the equipment. This applies particularly to the battery system, which requires special care to maintain reliable operation;

e) description of the range of other environmental conditions (e.g., humidity, pressure, shock and vibration, electromagnetic radiation) over which the defibrillator was tested and performs successfully, and optional description, with measurements if available, of the electromagnetic radiation emitted by the defibrillator during charge and discharge, since such radiation may cause nearby instruments or computers to malfunction;

f) description of adverse conditions (e.g., low battery, electromagnetic radiation, ECG artifact, pacemaker spikes, defibrillation recovery, or other environmental noise conditions) that may degrade the performance of cardiac rhythm interpretation or defibrillator operation;

g) specific instructions for operating the defibrillator using its battery system, including the steps for recharging the battery.

The instructions of 3.2(c) shall include a specific warning on the potential hazards of open and shorted electrode discharges to the operator and possibly to the equipment, if such operation is possible; and, in addition, a notice shall be placed in the instruction manual specifying the maximum time the defibrillator remains fully charged and the SHOCK control remains active.

A maintenance manual shall be available. It shall provide instructions on checking, maintaining, and servicing the equipment. It shall also include, where applicable, component replacement procedures, schematic circuit diagrams, and the address of one or more authorized repair facilities.

3.3 Essential requirements

3.3.1 Operating conditions

a) Defibrillators should be capable of operating successfully and meeting all performance specifications stated in this standard under the following ambient environmental conditions:

1) temperature: 0°C to 50°C, except when specifically noted;

2) relative humidity: 5 percent to 95 percent, noncondensing;

3) atmospheric pressure: 700 millibar (mbar) to 1060 mbar.

b) Unless otherwise stated, the performance requirements of this standard shall apply with a 50-ohm resistive load simulating the patient connected to the output.

3.3.2 Energy range

3.3.2.1 AEDs intended for EMS or hospital use

The maximum selectable delivered energy E_{MAX} shall be in the range of 250 to 360 joules (J). The maximum energy capability shall be clearly labeled on the device. The defibrillator shall provide a selection of energy output with a minimum of two levels, one in the 160 J to 200 J range and the other in the 250 J to 360 J range. Energy limits may be waived for defibrillators with "programmable" energy dosage for prescriptive use. (Cardioversion or internal discharge are not considered.)

3.3.2.2 AEDs intended for home or standby use

The device shall be capable of delivering an energy of not less than 200 J. A higher maximum energy, up to 360 J, is permissible.

3.3.3 Energy accuracy

The delivered pulse energy shall be within ± 15 percent of the selected energy indicated on the energy level indicator of 3.3.11 when discharged into a 50-ohm resistive load. The delivered pulse energy shall be within ± 40 percent of the selected energy indicated on the energy level indicator of 3.3.11 when discharged into any resistive load between 25 and 100 ohms.

3.3.4 Pulse shape and duration

The pulse shape (waveform) shall be of either the damped sinusoidal or the truncated exponential type, and shall meet the specifications of the ANSI/AAMI DF2—1989 standard, *Cardiac defibrillator devices*.

3.3.5 Charge time

With batteries/battery fully charged and then depleted by 5 E_{MAX} discharges, a defibrillator shall be capable of charging to E_{MAX} within 15 seconds.

3.3.6 Battery capacity

The capacity of a new and fully charged battery shall be such that, at 0°C, the defibrillator provides at least 6 discharges of E_{MAX} at 30-second intervals.

3.3.7 Battery shelf life

3.3.7.1 AEDs for EMS/hospital use

After the battery is fully charged, the defibrillator shall be stored for 7 days at 20°C and 65 percent relative humidity. Afterwards, the defibrillator shall be capable of delivering 6 discharges of E_{MAX} at 30-second intervals. Charge time for the final discharge shall be less than 20 seconds.

3.3.7.2 AEDs for home/standby use

After the battery is fully charged, the defibrillator shall be stored for 90 days at 20°C and 65 percent relative humidity. Afterwards, the defibrillator shall be capable of delivering 6 discharges of E_{MAX} within 3 minutes—charge time for the final discharge shall not exceed 30 seconds.

3.3.7.3 AEDs with nonrechargeable batteries

If nonrechargeable batteries are used in a home defibrillator, new and unused batteries with a shelf life of at least 1 year shall meet the specifications of 3.3.6 (capacity) after 1 year of storage.

3.3.8 Energy loss rate

For defibrillators with a discharge control, the defibrillator shall be capable of delivering a pulse of not less than 85 percent of the initial deliverable energy at temperatures of up to 50°C for the duration of the period before automatic disarm (see section 3.3.9) is activated.

3.3.9 Automatic disarm

A charged defibrillator shall automatically disarm if not intentionally discharged within a certain period. Automatic disarm normally shall occur at not less than 10 seconds and not more than 30 seconds after completion of charge. The length of this period shall be disclosed in the operating instructions of 3.2(a).

3.3.10 Controls and indicators

Those controls and indicators required to bring the defibrillator from the OFF condition to the state where an energy pulse of the desired level can be delivered to the patient shall be functionally grouped in a clearly defined area, inclusive outline, or an easily distinguishable contrasting patch. The controls and indicators within the defined outline shall be limited to the following, individually or in combination:

a) ON/OFF control and ON indicator;

b) DISARM markings;

c) energy level indicator;

d) charge indicator;

e) energy select control (if available);

f) charge control (if available);

g) discharge control (if available);

h) mode control (manual or automatic).

If the defibrillator control panel contains no controls and indicators other than those itemized in (a), (b), (e), (f) and (g), the defined area shall not be required.

3.3.11 Energy level indicator

The defibrillator shall have a means to clearly indicate to the operator the energy that will be delivered into a 50-ohm test load. Any other indicators shall be secondary to this delivered energy indication.

3.3.12 Charge indicator

A distinct visual indicator shall be provided to clearly indicate that the defibrillator is ready to deliver at least 85 percent of the selected energy. The same indicating device may also display the charging or discharged state of the defibrillator.

3.3.13 Low battery charge indicator

A means shall be provided by which the defibrillator operator may determine when nonrechargeable batteries require replacement or when rechargeable batteries require charging. The defibrillator shall be capable of at least three charge and discharge cycles at E_{MAX} after the Low Battery Charge Indicator has activated, at 20°C. If nonrechargeable batteries are used, e.g., in a home defibrillator, an active low battery warning shall be provided along with a label showing the expiration (replacement) date of the battery.

3.3.14 Charge control

Depending on the configuration of the defibrillator, a charge control which initiates charging of the internal

energy storage device may be incorporated.

3.3.15 Discharge control

Depending on the configuration of the defibrillator, a discharge control which initiates discharge of the selected energy into the patient circuit may be incorporated.

3.3.16 Disarm

Ten seconds after removal of power to the functional circuits, by operation of the ON/OFF control or by other means, the defibrillator shall not present a voltage at the electrodes.

3.3.17 Defibrillator protection

If an AED was applied to a patient, defibrillation attempts were unsuccessful, and a second defibrillator becomes available and is intended for use, it is recommended that the AED electrodes be removed and the AED be disconnected before the second defibrillator is used. However, if the operator fails to remove the AED electrodes and proceeds to defibrillate with the second defibrillator, the AED and its electrodes should be so designed that operation of the second defibrillator does not damage the AED, defibrillation is not impaired by the presence of the AED, and the operator or other bystanders are not exposed to electrical shock. The manufacturer shall disclose whether the AED meets these requirements or not.

3.3.17.1 Recovery

The AED, after a maximum period of 10 seconds following a 360 J discharge from a second defibrillator, shall be capable of functional rhythm recognition analysis.

In addition, for AEDs providing a cardiac monitor display, recovery shall occur within 10 seconds after defibrillation to display a test signal at least 50 percent of the peak-to-valley amplitude of the original test signal.

The AED shall be capable of resuming functional rhythm analysis within 10 seconds after its own discharge of E_{MAX}.

3.3.17.2 Energy shunting

The design of the AED and its electrodes shall be such (e.g., by incorporation of current limiting devices) that the energy delivered to a 100-ohm load (which simulates a high-impedance patient) by a second defibrillator is reduced by not more than 10 percent due to shunting by the AED.

3.3.17.3 Operator safety

The AED shall be capable of exposure to a 360 J discharge from a second defibrillator without exposing hazardous electrical energy to other accessible parts of the AED. The charge passed to ground through the chassis or controls of the AED shall not exceed 100 microcoulombs (μC).

3.3.18 Rhythm recognition detector

3.3.18.1 Function of rhythm recognition detector

a) The ECG rhythm recognition detector shall differentiate shockable rhythms from all other cardiac rhythms including normal sinus rhythm, supraventricular rhythms such as atrial fibrillation and atrial flutter, ventricular ectopy, idioventricular rhythms, and asystole. Spontaneous organized cardiac rhythms, associated with the presence of pulse and blood pressure, frequently follow defibrillation. The AED shall be designed not to shock such organized cardiac rhythms.

Shockable rhythms shall include ventricular fibrillation (VF) and may include ventricular tachycardia (VT). The manufacturer will clearly state in labeling the rhythms designated as shockable, and the

criteria used to identify "shockable" VT.

b) The detection, analysis time, and defibrillator charging time to E_{MAX} shall not exceed a total of 30 seconds.

c) The detector may initiate analysis of the rhythm either automatically or following manual initiation by the device operator. In either case, analysis shall not be initiated until there is a positive indication of good electrode contact.

1) For those devices that automatically initiate analysis, a clear indication of device status shall be given to the operator. The device shall immediately communicate its decision or recommendation to the operator upon charge initiation. No more than three successive detection episodes that include shock delivery with each episode will be allowed to occur automatically. After the third shock, operator intervention may be required to initiate a new sequence of analysis and shock delivery episodes if additional shocks are desired and allowed by protocol. The actual device protocol shall be clearly indicated on the device. If an automatic sequence is stopped either by the operator or by the device, up to three detection episodes including shock delivery are allowed upon reinitiation by the operator.

2) For those devices in which manual initiation of analysis by the device operator is employed, a minimum of three consecutive detection/shock episodes shall be allowed. Any disabling of the detector shall be clearly indicated on the device.

d) The sensitivity for recognizing VF at 200 microvolts (μV) or greater amplitude shall exceed 90 percent in the absence of artifacts (e.g., induced by cardiopulmonary resuscitation). For those devices which detect VT, the sensitivity shall exceed 75 percent; however, additional criteria (which may require the operator's intervention) will be required to support a shock decision. The specificity of the detector in correctly identifying nonshockable rhythms shall exceed 95 percent in the absence of artifacts.

3.3.18.2 Databases and test report

3.3.18.2.1 Test database

The test database for determination of sensitivity and specificity shall include at a minimum VF rhythms of varying amplitudes, VT rhythms of varying rates and QRS width, various sinus rhythms including supraventricular tachycardias, atrial fibrillation and atrial flutter, sinus rhythm with premature ventricular contractions (PVC), asystole and pacemaker rhythms. All rhythms shall have been collected using electrode systems and preamplifier characteristics similar to the device being tested, and shall be of appropriate length to allow decisions to be made by the detector system. The database rhythms used to test device performance shall be maintained separately from rhythms used for detector development. The device labeling shall include a summary of the rhythms used for testing.

3.3.18.2.2 Test report

A test report describing recording methods, rhythm source, how the rhythms were chosen, and the annotation methods and criteria shall be available.

The results of any detector performance shall be reported as follows:

Table 1—Table for displaying results of detector performance

	VENTRICULAR FIBRILLATION VENTRICULAR TACHYCARDIA	ALL OTHER ECG RHYTHMS
SHOCK	A	B
NO SHOCK	C	D

a) A true positive (A) is a correct classification of a shockable rhythm.

b) A true negative (D) is a correct classification of all rhythms other than those in which shocks are indicated.

c) A false positive (B) is an organized or perfusing rhythm that has been incorrectly classified as a shockable rhythm or condition.

d) A false negative (C) is VF or VT associated with cardiac arrest that has been classified as nonshockable.

e) The sensitivity of the device for the shockable rhythms is A/A+C. The true predictive value is the number of true positives expressed as a percentage of the total number of rhythms classified as shockable; i.e., A/A+B.

f) The false positive rate is the percentage of organized rhythms that have been incorrectly classified as shockable rhythms and is expressed as B/B+D. The specificity is the number of organized or perfusing rhythms that have been correctly classified as nonshockable rhythms by the detector and is expressed as D/B+D.

3.3.18.2.3 Performance summary

The report shall clearly summarize the sensitivity for detecting VF, and the sensitivity for detecting VT for those devices designed to treat VT. The positive predictive accuracy, the false positive rate, and the overall specificity of the device shall also be reported. Reporting the specificity of the device for each nonshockable rhythm group (i.e., normal sinus rhythm, supraventricular rhythms such as atrial fibrillation and atrial flutter, ventricular ectopy, idioventricular rhythms, and asystole) is also recommended.

3.3.18.3 Secondary detector systems

Secondary detector systems to aid the device operator may be provided. The device labeling shall clearly describe the method of operation of any secondary detector system and the criteria for recommending shock delivery. Test documentation should be provided, showing that the secondary detector system is useful and does not inappropriately delay or stop treatment of cardiac arrest victims.

3.3.19 Self-adhesive electrodes for monitoring and defibrillation, and optionally pacing

3.3.19.1 AC small signal impedance

The average value of 10 hertz (Hz) impedance for at least 12 electrode pairs connected gel-to-gel, at a level of impressed current not exceeding 100 microamperes (μA) peak-to-peak (p-p), shall not exceed 2 kilohms. None of the individual pair impedances shall exceed 3 kilohms. The impedance at 30 kHz shall be less than 5 ohms.

3.3.19.2 AC large signal impedance

The impedance of an electrode pair connected gel-to-gel, in series with a 50-ohm load and measured at E_{MAX} shall not exceed 2 ohms.

3.3.19.3 Combined offset instability and internal noise

A pair of electrodes connected gel-to-gel shall, after a 1-minute stabilization period, generate a voltage no greater than 150 μV peak-to-peak in the passband of 0.15 to 100Hz, for a period of 5 minutes following the stabilization period.

3.3.19.4 Defibrillation overload recovery

The potential of a pair of electrodes connected to a 50-ohm test load and subjected to three E_{MAX} shocks at 1-minute intervals shall not exceed 400mV at 4 seconds and 300mV at 60 seconds after the last shock delivery.

3.3.19.5 Dielectric strength

For a voltage of 1.5 times the maximum voltage occurring on the energy storage capacitor, the leakage current flowing between the active part and the insulated backing of the electrode shall not exceed 250μA.

3.3.19.6 DC offset voltage

A pair of electrodes connected gel-to-gel shall, after a 1-minute stabilization period, exhibit an offset voltage no greater than 100mV.

3.3.19.7 Bias current tolerance

The observed dc voltage offset change across a pair of electrodes connected gel-to-gel shall not exceed 100mV when the electrode pair is subjected to a continuous 200 nanoampere (nA) dc current over the period recommended by the manufacturer for the clinical use of the electrodes (but not less than 8 hours).

3.3.19.8 Electrode active area

The minimum active (gel) area of individual self-adhesive electrodes used for adult defibrillation and pacing shall be at least 50 cm^2 and the total area of the two electrodes shall be at least 150 cm^2.

3.3.19.9 Electrode adhesion and contact to patient

The electrode materials and construction shall ensure good adhesion and electrical contact with the patient when the electrodes are placed properly. The characteristics of the adhesive (peel strength, setting time, response to perspiration, effect of temperature of these characteristics) should be available from the vendor.

3.3.19.10 Packaging and shelf life

The device shall be manufactured and packaged in such a way that all requirements of this standard will be met up to the expiration date, and under the storage conditions specified by the manufacturer. At a minimum, electrodes shall comply with all performance specifications after storage of 1 year at temperatures in the range of 15°C to 35°C, and/or after 12 hours exposure to temperatures ranging from -30°C to +65°C (electrodes shall be returned to a temperature in the 15°C to 35°C range before the specifications test is performed).

3.3.19.11 Universal function electrodes

If the electrodes are designed and intended for use in all three modes, i.e., monitoring and defibrillation, and optionally pacing, the following requirements apply:

a) The electrode package shall clearly identify all functions that the electrode will perform.

b) The electrode package shall provide specific instructions for the connection, placement, and operation of the electrodes for their various functions.

c) The electrodes shall meet all requirements of 3.3.19 after 60 minutes of pacing at the maximum current output and maximum pacing rate through a pair of gel-to-gel electrodes in series with a 50-ohm resistor unless the ECG amplifier has been designed specifically to compensate for large dc offsets.

3.3.19.12 Cable length

The electrode cables shall have an extended length of at least 2 meters.

3.3.20 Event documentation

3.3.20.1 Purpose

The purpose of event documentation is to allow medical control authority to:

a) identify whether the device was operated correctly by the user;

b) determine the performance of the device, as a conventional manually operated defibrillator, during clinical use (if the device can operate in the manual mode);

c) determine the performance of the device, as an automatic or semiautomatic defibrillator, during clinical use.

3.3.20.2 Methods of documentation

Event documentation may be achieved by magnetic tape cassettes, solid-state electronic storage modules or cards, or other functionally equivalent means. Retrospective review of stored information may be performed using either the AED or an accessory system.

3.3.20.3 Information content of event documentation

The information content shall be sufficient to allow full retrospective review of the event by the medical control authority. For that purpose, information recorded and reported should include the following:

a) date of the clinical use;

b) device-specific information including device serial number and software revision level if applicable;

c) time when the device was turned on. This time serves as a zero time reference. All subsequent events may be timed in either absolute or elapsed time;

d) time when the electrodes were applied to the patient;

e) initial rhythm;

f) each time analysis was initiated, rhythm during analysis period and result of the analysis (shock indicated or not);

g) time of each shock, nominal delivered energy selected (by the device or the operator), and, optionally, other discharge parameters (e.g., peak current, impedance);

h) rhythm following each shock;

i) occurrence of any artifactual problems (e.g., due to patient motion or cardiopulmonary resuscitation [CPR]) if such problems caused the analysis to abort;

j) time when the device was turned off.

Some of that information may be available on the recorder if the defibrillator is equipped with a recorder. Other information may be stored in the device and subsequently retrieved. Additional information may be provided by the device operator, particularly patient status.

3.3.21 Electromagnetic compatibility (EMC) requirements

These EMC requirements were developed on the basis of reference standards 2.1.5, 2.1.6, and 2.1.8.

3.3.21.1 Electromagnetic emissions

3.3.21.1.1 Radiated and conducted EM emissions

The instrument (AED or RCD) shall comply with the requirements of International Special Committee on Radio Interference (CISPR) 11, group 1, level B in the worst case configuration and operating mode.

Emission levels measured 10 meters from the instrument shall not exceed 30 decibels (dB) μV from 30 Hz to 230 MHz and shall not exceed 37 dB μV from 230 to 1000 MHz.

NOTE—These requirements are waived during a defibrillator charge/discharge cycle.

3.3.21.1.2 Magnetic field emissions

The unit shall not emit a magnetic field greater than .5 millitesla (5 gauss) at any point on the surface of the instrument under normal operating conditions. This requirement does not apply during the charge/discharge cycle.

3.3.21.2 Electromagnetic immunity

3.3.21.2.1 Immunity to radiated rf EM fields

The test methods and instruments specified in International Electrotechnical Commission (IEC) 801-3 apply.

The instrument is exposed to a modulated rf field with the following characteristics:

a) field strength: 3V/m (level 2);

b) carrier frequency range: 26 MHz to 1 GHz;

c) AM modulation, 80 percent index, at 3 frequencies: 1, 5, and 20 Hz.

The AED's combination defibrillator/monitoring electrodes are terminated in a simulated patient load (1 kohm resistor in parallel with a 1μF capacitor). The instrument is tested with all its faces sequentially exposed to the rf field.

When exposed to a level 2 field (3V/m), no inadvertent discharge or other unintended change of state shall occur. An increase in ECG noise level up to 100 μV peak-to-peak is allowed, but the noise induced in the ECG passband shall not cause the VF detection algorithm to give false positive QRS or VF detections.

When exposed to a level 3 field (10V/m), no inadvertent discharge is allowed.

NOTE—Certain patient cable configurations may cause failure to meet these immunity requirements. In such a case, the manufacturer shall disclose the reduced immunity levels which are met.

3.3.21.2.2 Immunity to conducted EM fields

The test methods and instruments specified in the current draft of IEC 801-6 apply.

When an AED/RCD can be operated from line power as well as battery, an rf noise voltage with the following characteristics is injected into the input power cord (not in the signal input):

a) noise voltage amplitude: 1 V RMS;

b) carrier frequency: 150 KHz to 230 MHz;

c) AM modulation, 80 percent index, at 1, 5, and 20 Hz.

No inadvertent discharge or other unintentional change of state shall occur during this period. No degradation of system performance or loss of functionality is allowed.

3.3.21.2.3 Immunity to magnetic fields

The equipment is exposed to an ac magnetic field of variable frequency:

a) magnetic field intensity: 10^{-4} tesla peak-to-peak (1 gauss);

b) frequency range: 47.5 to 1320 Hz.

The equipment is exposed on all faces. The ECG leads and electrodes are short-circuited at the instrument. No inadvertent discharge or other unintentional change of state shall occur during this test. Some display jitter is allowed; however, the displayed information shall be readable.

3.3.21.2.4 Immunity to electrostatic discharge (ESD)

The test methods and instruments specified in IEC 801-2 apply.

The instrument is exposed, at any point on its surface accessible to the operator or patient, to open air discharges up to 8kV or direct contact discharges up to 4 kV, both positive and negative.

Condition 1. For open air discharges up to 4 kV and direct contact discharges up to 2 kV, the user shall not notice any change in equipment operation. The equipment shall operate within normal limits of its specifications. No degradation of system performance or loss of functionality is allowed. However, ECG spikes, display glitches, or momentary light emitting diode (LED) flashes are acceptable during an ESD discharge.

Condition 2. For open air discharges up to 8 kV or direct contact discharges up to 4 kV, the equipment may exhibit momentary loss of functionality but shall recover within 2 seconds without user intervention.

3.3.21.2.5 Power line transients

a) *Fast transient/bursts*. The test methods and instruments specified in IEC 801-4 apply. Mains connectable instruments shall meet a 1 kV immunity level at the mains plug. Only transient loss of functionality is allowed. The device should revert to its condition just prior to the burst without operator intervention.

b) *Surge immunity*. The test methods and instruments in the current draft of IEC 801-5 apply. Mains connectable equipment shall meet an immunity level of 1 kV line-to-line and 2 kV line-to-ground. No inadvertent discharge or other unintentional change of state is allowed. The device should revert to its prior condition without operator intervention.

3.4 External pacing

External pacing capability may be provided as an optional feature.

3.4.1 Pacing mode activation

The pacing mode may be activated either by manual or automatic control.

a) If pacing operation is manually controlled by the operator, the control used to activate pacing will be labeled PACING ON/OFF or equivalent means.

b) If pacing operation is automatically activated by the device as part of its operating protocol, the interaction of pacing mode operation with the defibrillation protocol will be described in the operating instructions.

c) The defibrillator will be disarmed and the defibrillation mode will be disabled when the pacing mode is operative.

3.4.2 Pacing mode indicator

Indication will be provided when the external pacing mode is operative.

3.4.3 Pacing delivery

The pacing output may be delivered to the patient through either the defibrillation electrode pathway or a separate pacing electrode pathway.

3.4.3.1 Separate pacing pathway

If a separate pacing electrode pathway is provided, the following apply:

a) Pacing electrode placement and connection shall be described in the operating instructions.

b) The pacing output circuitry shall be able to withstand without damage three 360 J defibrillation discharges 1 minute apart across the pacing electrode pads shunted by a 100-ohm load.

3.4.3.2 Combined pathway

If the defibrillation/pacing electrode pathway is also used for ECG monitoring, the following will apply:

a) The electrode package shall clearly identify the function the electrode will perform.

b) Electrode placement and connection shall be described in the operating instructions.

c) The electrodes shall meet all of the requirements of section 3.3.19.11.

3.4.4 Pacing pulse shape and duration

The pacing pulse shape (waveform) and duration shall be specified in the operating instructions.

3.4.5 Pacing pulse current

If predetermined within the pacer, the pacing pulse current shall be described in the operating instructions. If operator selection is provided, the control that selects the pacing pulse current shall be labeled OUTPUT (milliampere [mA]) with the selected current level indicated.

3.4.6 Pacing rate

If predetermined within the pacer, the pacing rate shall be described in the operating instructions. If operator selection is provided, the control that selects the pacing rate shall be labeled RATE (pulses per minute) with the selected rate indicated.

3.4.7 Pacing protocol

Pacing may be provided in either a continuous or intermittent sequence. If predetermined within the pacer, the pacing protocol shall be described in the operating instructions. If operator selection is provided, the control that selects the pacing protocol will be appropriately labeled with the available selections.

3.4.8 Pacing sensitivity

If predetermined within the pacer, the cardiac rhythm interpretation criteria used to activate pacing operation shall be described in the operating instructions. If operator selection is provided, the control that selects the pacing sensitivity will be labeled SENSITIVITY (mV) with the selected ECG signal triggering level appropriately indicated.

3.4.9 Demand pacing

Demand pacing is not a required feature of AEDs including external pacing capability.

3.5 Remote-control defibrillators

An RCD is a portable device connected to a base station by a communications link. ECG and electrode impedance data from the patient and human voice are transmitted to the base station, where data are displayed to a listening, communicating human operator. The operator controls the energy select, charge, and discharge functions of the portable defibrillator by remote-control signals which are transmitted by the communications link. The base station operator's decision to defibrillate is based upon voice confirmation from a witness that the patient is unconscious, upon impedance telemetry showing adequate electrode contact, and upon ECG telemetry showing VF, VT, or supraventricular tachycardia with loss of consciousness.

An RCD consists of seven basic subunits:

a) a speakerphone or radiotelephone;

b) an ECG amplifier, telemetry unit and display;

c) an electrode impedance and telemetry unit;

d) a standard defibrillator with the energy select, charge, discharge, and disarm or dump charge manual switches being replaced by remotely controlled switches (communications link);

e) a communications link that interfaces the portable patient unit to the controlling base station;

f) a controlling base station that provides display and permanent documentation of ECG impedance, voice, and defibrillation control command signals;

g) a battery charging element and battery management circuits.

3.5.1 Audio quality

The audio quality for the speakerphone connection between the patient and/or witness and the base station operator shall be sufficient to enable clearly understandable speech. Thus, the frequency response from base station microphone to patient unit speaker and from patient unit microphone to base station speaker shall be at least 300 Hz to 2500 Hz.

3.5.2 ECG quality

The ECG telemetry subunit should transmit and ultimately display to the operator an ECG of at least 1 Hz to 30 Hz frequency response on a standard memory display in order to enable proper human interpretation of the ECG waveform.

3.5.3 Measurement of patient and electrode impedance

An RCD should measure the patient transthoracic impedance (TTI), including the electrode-skin impedance, relay the measurement by telemetry, and display the TTI value at the base unit. The measurement should be accurate within ± 10 percent standard deviation (± 20 percent range). The physician at the base unit can then use the impedance measurement as a quality control tool to verify correct electrode placement and good electrical contact between electrodes and patient, and exercise his judgment on whether or not to proceed

with defibrillation. In addition, the RCD may automatically prevent defibrillation if the measured impedance is abnormally low or high.

3.5.4 Compliance with referenced standards (2.1)

The defibrillator subunits shall comply with all AAMI standards for manual defibrillators or AEDs, with the exception of labeling requirements and manual switch control requirements. If synchronized cardioversion is offered, it shall also comply with the AAMI standard for manual defibrillators with the exception that it is permissible to have a time delay of less than 5 seconds between initiation and delivery of the enabling pulse. The actual delivery of the shock to the patient shall be synchronized. It is essential that once charged, a remotely controlled defibrillator automatically disarm in 30 seconds, even if a disruption in the communication link occurs disconnecting the portable defibrillator unit from base station control.

3.5.5 Device labeling

RCDs intended for home use shall be operable only under the control of trained remote personnel. Clear operating instructions shall be printed on the case of the device listing:

a) how to dial base station (if manual dial is required or if auto dial fails);

b) how to place electrodes on patient's chest;

c) how to turn the portable unit on (except in units that automatically turn on when opening the instrument's case).

Other warning labels or messages should be in compliance with the present standard. Manufacturers should provide training manuals to potential patients and witnesses, and oversee installation procedures to ensure that the device and the communication link work properly in the installed location. Manufacturers should also provide training manuals and training to medical personnel who will be operating base stations. Use limitations should be clearly defined and communicated to the base station operators and to users such as the patient and/or witness.

3.5.6 Base station requirements

The base station should contain a display section capable of nonfade display of ECG signals with a bandwidth of at least 1 Hz to 30 Hz, impedance display as per section 3.5.3, a voice communication system with minimum frequency response of 300 Hz to 2500 Hz, and defibrillation controls configured in a similar fashion to the 1, 2, 3 charge select, charge, discharge, disarm, and synchronizer controls of manual defibrillators. The base station shall have a system of permanent documentation of ECG, impedance, voice, and defibrillation command controls.

3.5.7 Battery system

The battery charging and battery management mechanism shall provide energy to recharge the remote unit's internal batteries. It shall also monitor the condition of these batteries. The subunit shall provide an indication that the batteries are being charged as well as a warning should the state of the battery compromise the operation of the remote unit. Battery status information shall be made available to base station operators over the communications link.

After completely recharging the batteries, a remotely controlled defibrillator unit should have a continuous ECG/voice telemetry monitoring time of greater than 30 minutes.

3.5.8 Scheduled system testing

The base unit shall be tested for all functional characteristics at least once a year.

3.5.9 Communications link and device communication interface

The communications link of an RCD is the mechanism by which information is exchanged between the remote defibrillator device and the controlling base station. Information to be transferred includes voice, ECG, and impedance data, and the command codes that operate the defibrillator and/or that adjust gains or filters of the data channels. At present, the link utilizes standard landline telephones. In the future, the link may utilize cellular, radio, fiberoptic, or other transmission methods. These may require additions or modifications to this standard.

3.5.9.1 Performance requirements of the device communication interface

For safe operation of the RCD, the communication link shall have sufficient frequency response (minimum 300 Hz to 2500 Hz) to pass the human voice, telemetered ECG, impedance data, and control signals.

The device communication interface shall have sufficient protection so that the defibrillator cannot charge or discharge due to any single component failure or due to random noise.

The system should automatically establish a communication link within 30 seconds. Should the link fail, the RCD should detect the failure and attempt to reestablish the link within 30 seconds.

The device communication interface shall provide automatic notification within 30 seconds to the operator and to the patient or bystander if the link fails, so that they may proceed manually to dial the emergency medical service.

The error rate in establishing communications should not exceed 0.5 percent for 95 percent of transmission.

Patients and witnesses should be trained to call another emergency phone number if the automatic dialing and establishment of the link is not accomplished after 1 minute.

4 Tests

As stated in the foreword, the tests described in this section are primarily intended for use in design qualification or "type" evaluation by device manufacturers, and may not all be appropriate for users.

4.1 Device labeling

a) Choose a representative sample of the device marking, and wipe it thoroughly with a folded cheesecloth applicator saturated in a cleaning agent specified in the manufacturer's cleaning instructions;

b) Repeat the wiping procedure four times;

c) Chipping, peeling, or deterioration of the contrast ratio of the markings should not be visible.

Compliance with the remainder of the device labeling requirements of 3.1 can be verified by inspection.

4.2 Operating instructions and maintenance manuals

Compliance with the requirements of 3.2 can be verified by inspection.

4.3 Essential performance requirements

4.3.1 Operating conditions

4.3.1.1 Test apparatus

The following types of apparatus are required for performing the tests of subsection 4.3.1: defibrillator tester; dual-channel storage oscilloscope; oscilloscope camera or other suitable instrument(s) for recording an analog waveform; pulse generator; ac/dc voltmeter; ac milliammeter; ohmmeter; timer; 25-ohm, 50-ohm, and 100-ohm resistive test loads with sufficient energy absorptive capability (E_{MAX}); ac high-potential tester; wire and the test apparatus needed for evaluating risk currents; temperature and humidity chambers capable of 0°C to 50°C and 65 percent ± 5 percent RH, described in ANSI/AAMI ES1—1985. Note that

special modifications may be required to the defibrillator tester and other equipment in order to allow for discharges of automatic defibrillators. Such modifications should be clearly identified and documented and should not affect test equipment accuracy or calibration.

4.3.1.2 Accuracy

The accuracy of instruments and test equipment used to control or monitor the test parameters shall be verified at appropriate intervals, documented, and a calibration sticker shall be affixed to the instrument. All instruments and test equipment used in conducting the tests specified herein shall:

a) conform, where possible, to laboratory standards whose calibration is traceable to the prime standards at the National Institute of Standards and Technology;

b) have the greatest feasible accuracy and no more than one-third the tolerance of the variable to be measured, or ± 5 percent of the variable being measured where only maximum or minimum limits are given;

c) be appropriate for measuring the test parameters.

4.3.1.3 Low temperature tests

For all tests of defibrillators at 0°C, the defibrillator shall be placed in an environmental temperature of 0° C for a minimum of 2 hours prior to the test to allow equilibration of the defibrillator components to the environmental temperature.

4.3.2 Energy range

a) Attach the defibrillator to the defibrillator tester;

b) Inspect the energy select control, if available, or the operating instructions and verify that E_{MAX} is between 250 J and 360 J inclusive and also verify that at least one other energy is available between 160 J and 200 J;

c) Select E_{MAX} if energy is selectable or deliver the appropriate number of shocks to allow the defibrillator to select E_{MAX};

d) Upon completion of the charge, discharge the defibrillator if a discharge control is available or allow the defibrillator to automatically discharge;

e) The delivered energy indicated on the tester shall be within ± 15 percent of E_{MAX}, as indicated on the energy level indicator or as indicated in the operating instructions.

4.3.3 Energy accuracy

a) Attach the defibrillator to the defibrillator tester;

b) Select E_{MAX} and initiate the charge as described in 4.3.2;

c) Immediately upon completion of the charge, discharge the defibrillator or allow the defibrillator to discharge automatically;

d) The delivered energy indicated on the tester shall be within ± 15 percent, whichever is greater, of the indicated energy;

e) Connect an additional 50-ohm resistive test load across the input to the defibrillator tester, creating an effective 25-ohm load for the defibrillator;

f) Repeat steps (b) and (c). The delivered energy indicated on the tester shall be within ± 40 percent of one-half the indicated energy;

g) Reconnect the additional 50-ohm resistive test load in series with one input to the defibrillator tester creating an effective 100-ohm load for the defibrillator;

h) Repeat steps (b) and (c). The delivered energy indicated on the tester shall be within ± 40 percent of one-half the indicated energy;

i) Repeat steps (b) through (h) for each available energy.

NOTE—The above test is based upon a defibrillator tester calibrated for a 50-ohm resistive load. Therefore, in steps (f) and (h) factors of one-half appear.

4.3.4 Pulse shape and duration

Reference tests described in ANSI/AAMI DF2—1989.

4.3.5 Charge time

a) Fully charge the battery according to the operating instructions. Install a fresh battery;

b) Attach the defibrillator to the defibrillator tester;

c) Perform 5 charge and discharge cycles at E_{MAX} waiting 20 seconds between each cycle if possible or by initiating the appropriate number(s) of automatic cycles to deliver the 5 cycles;

d) Select E_{MAX}, or allow the defibrillator to deliver the appropriate number of charge/discharge cycles to automatically select E_{MAX};

e) Simultaneously initiate the charge and a timer. If an analysis cycle precedes the charge, initiate the timer with the beginning of the charge, not the analysis;

f) Verify that the charge time is less than 15 seconds.

4.3.6 Battery capacity

a) Fully charge the battery according to the operating instructions or install a fully charged battery. Establish an environmental temperature of 0°C and let the defibrillator equilibrate for at least 2 hours at 0°C;

b) Attach the defibrillator to the defibrillator tester and select an energy of E_{MAX} if energy is selectable;

c) Simultaneously start the analysis/charge and a timer;

d) Perform 6 discharges in sequence waiting 30 seconds between each successive discharge.

4.3.7 Battery shelf life

4.3.7.1 AEDs for EMS/hospital use

a) After fully charging the battery, store the device in an unenergized state for 7 days at 20°C ± 2°C and a relative humidity of 65 percent ± 5 percent;

b) Attach the defibrillator to the defibrillator tester and select an energy of E_{MAX} if energy is selectable;

c) Simultaneously initiate analysis/charge and the timer;

d) Repeatedly charge/discharge the defibrillator at 30-second intervals for a total of 6 discharges or initiate automatic charge/discharge cycles until 6 discharges have occurred;

e) Verify that 6 discharges have occurred and that the charge time for the final discharge is less than 20 seconds.

4.3.7.2 AEDs for home/standby use

a) Direct test.

1) After fully charging the battery, store the device in an unenergized (off) state for 90 days at 20°C ± 2°C and a relative humidity of 65 percent ± 5 percent;

2) Attach the defibrillator to the defibrillator tester and select an energy of E_{MAX} if energy is selectable;

3) Simultaneously initiate analysis/charge and the timer;

4) Repeatedly charge/discharge the defibrillator for a total of 6 discharges or initiate automatic charge and discharge cycles until 6 discharges have occurred;

5) Verify that the 6 discharges have occurred within 3 minutes.

b) Alternative method.

Since the storage of devices for 90 days at fixed temperature and humidity is time consuming, difficult, or impractical, the AED manufacturer may rely on the battery manufacturer's specifications to determine that the device would successfully pass if the direct tests were performed.

4.3.7.3 AEDs with nonrechargeable batteries

a) Direct test.

1) Store 10 batteries either separately or installed in a defibrillator at 20°C ± 2°C and a relative humidity of 65 percent ± 5 percent for a period of 1 year;

2) Attach the defibrillator to the defibrillator tester and select an energy of E_{MAX} if energy is selectable;

3) Simultaneously initiate analysis/charge and the timer;

4) Repeatedly charge/discharge the defibrillator for a total of 6 discharges or initiate automatic charge and discharge cycles until 6 discharges have occurred;

5) Verify that the 6 discharges have occurred within 3 minutes for each of the 10 batteries.

b) Alternative method.

Since the storage of devices for 1 year at fixed temperature and humidity is time consuming, difficult, or impractical, the AED manufacturer may relay on the battery manufacturer's specifications to determine that the device would successfully pass if the direct test were performed.

4.3.8 Energy loss rate

a) Attach the defibrillator to the defibrillator tester;

b) Select E_{MAX}, initiate the analysis/charge, and discharge the defibrillator immediately upon completion of the charge. Note the indicated delivered energy on the tester;

c) Select E_{MAX}, initiate the analysis/charge, but do not discharge the defibrillator until just before automatic disarm would be activated. Note the indicated delivered energy on the tester;

d) The energy level noted in step (c) shall be no less than 85 percent of that noted in step (b).

NOTE—This test applies only to those defibrillators with a discharge control.

4.3.9 Automatic disarm

a) Attach the defibrillator to the defibrillator tester;

b) Select E_{MAX}, if energy is selectable; initiate the analysis/charge and start the timer at the moment that charging is complete;

c) Note the time when automatic disarm is activated. Verify that this time is between 10 and 30 seconds. Also verify that the device indicated automatic disarm;

d) Inspect the operating instructions to verify disclosure of the automatic disarm time and compare the disclosed time with that in step (c).

NOTE—This test only applies to those devices with discharge controls.

4.3.10-12 Controls and indicators

Compliance with these requirements can be verified by inspection.

4.3.13 Low battery charge indicator

a) Charge and discharge the defibrillator at E_{MAX} or the automatically selected energy every 30 seconds until the low battery discharge indicator activates;

b) Verify that the defibrillator is capable of at least three more charge and discharge cycles at E_{MAX} if energy is selectable.

NOTE—If nonrechargeable batteries are used, an active low battery warning shall be provided along with a label showing the expiration (replacement) date of the battery.

4.3.14-15 Charge and discharge control

Compliance with these requirements can be verified by inspection.

4.3.16 Disarm

a) Connect the defibrillator to the defibrillator tester;

b) Connect a storage oscilloscope or strip chart recorder having dc coupling differential mode capability across the defibrillator tester;

c) Activate the analysis/charge control and let the defibrillator charge to E_{MAX} if energy is selectable;

d) Simultaneously turn off the power and start a timer;

e) At an elapsed time of 10 seconds observe the trace recorded on the oscilloscope or the strip chart recorder;

f) The peak voltage shall not exceed 0 volt ± 1 volt.

4.3.17 Defibrillator protection

For test purposes, the simulated defibrillator discharge shall have a damped sinusoidal waveform conforming to the limits specified in the ANSI/AAMI DF2—1989 standard, *Cardiac defibrillator devices*. The source generator shall have a minimum stored voltage of 5000 V, and the energy delivered to the test assembly shall be 360 J. The waveform shall be delivered into a 100-ohm load (simulating the patient), with 10 ohms interposed between the 100-ohm defibrillator load and one connection of the AED, as shown in figure 1.A (see next page).

WARNING—The test circuit shown in figures 1.A and 1.B (see page 16) for producing simulated

defibrillator pulses should be constructed and used with great caution to avoid danger to test personnel. It may be necessary to connect two 50-ohm resistors in series to obtain a test load of 100 ohms. This should be done carefully since the node connection of the resistors is at or near one-half of full defibrillator voltage.

4.3.17.1 Recovery

a) Connect the AED to the test circuit of figure 1.A. A defibrillator test load of 100 ohms, or its equivalent, shall be used;

b) Charge the capacitor to 5000 V, with switch S1 in position A. Discharge is accomplished by actuating S1 to position B for a period of 200 ms ± 100 ms. The capacitor shall be disconnected in order to remove residual voltages and to allow recovery to commence;

c) After 10 seconds, verify that the AED correctly displays the test signal at an amplitude at least 50 percent of its normal amplitude before the test;

d) After this test, the AED shall meet all performance requirements of this standard;

e) Perform the test 3 times, with at least 30-second separation between successive discharges.

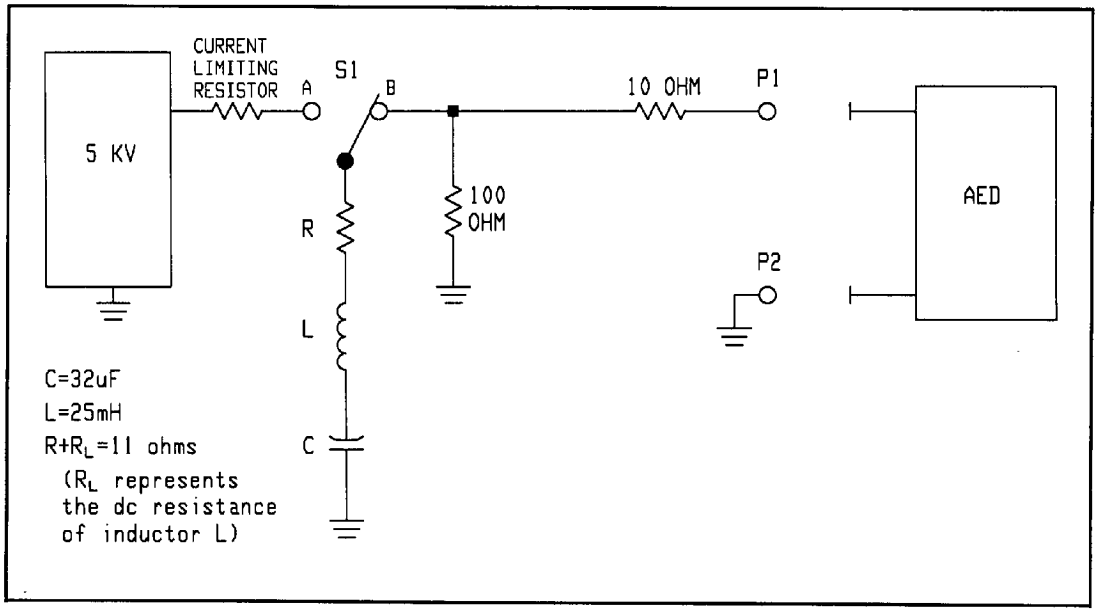

Figure 1.A—Test circuit for defibrillator overload tests (4.3.17.1 and 4.3.17.2). The switch S1 shall withstand peak currents of 60A in the closed position, and in the open position it shall not break down for voltages up to 5000 V.

NOTES—

1) The values of R, C, and L may be varied so long as the waveform conforms to the limits specifed in the ANSI/AAMI DF2—1989 standard.

2) The AEDs patient electrodes (or pads) shall be used.

3) Generally, the 100-ohm testload will consist of a 50-ohm load in series with the 50-ohm load of a defibrillator tester — with such a circuit, the total energy delivered to the 100-ohm load is twice the energy indicated by the defibrillator tester.

4.3.17.2 Energy shunting

a) Reconnect the AED to the test circuit of figure 1.A, discharge the test circuit, and measure the energy E1 delivered to the 100-ohm test load;

b) Remove the connections from the AED to P1 and P2, discharge the test circuit, and measure the energy E2 delivered to the test load;

c) Verify that the energy E1 is at least 90 percent of E2.

4.3.17.3 Operator safety

a) Turn the AED off. Connect the AED as shown in figure 1.B, where the "device chassis" connection is made as described in 4.3.17.1(c);

b) Discharge the test circuit and verify that the magnitude of the voltage V1 in figure 1.B is less than 1 volt.

4.3.18 Rhythm recognition detector

No specific test documentation is appropriate to this section due to possible variations in test databases and reports. Verify by inspection that a test report as described in 3.3.18.2 is provided. Verify also that the sensitivity and specificity requirements in 3.3.18.1 are met.

4.3.19 Self-adhesive electrodes for monitoring and defibrillation, and optionally pacing

4.3.19.1 AC small signal impedance

The impedance of a pair of electrodes connected to gel-to-gel can be determined by applying a sinusoidal current of known amplitude and observe the amplitude of the resulting voltage across the electrodes. The magnitude of the impedance is the ratio of the voltage to that of the current. An adequate current generator can be assembled utilizing a sinusoidal signal (voltage) generator with a 1-megohm resistor in series with the electrode pair. The level of the impressed current should not exceed 100 mA peak-to-peak (p-p).

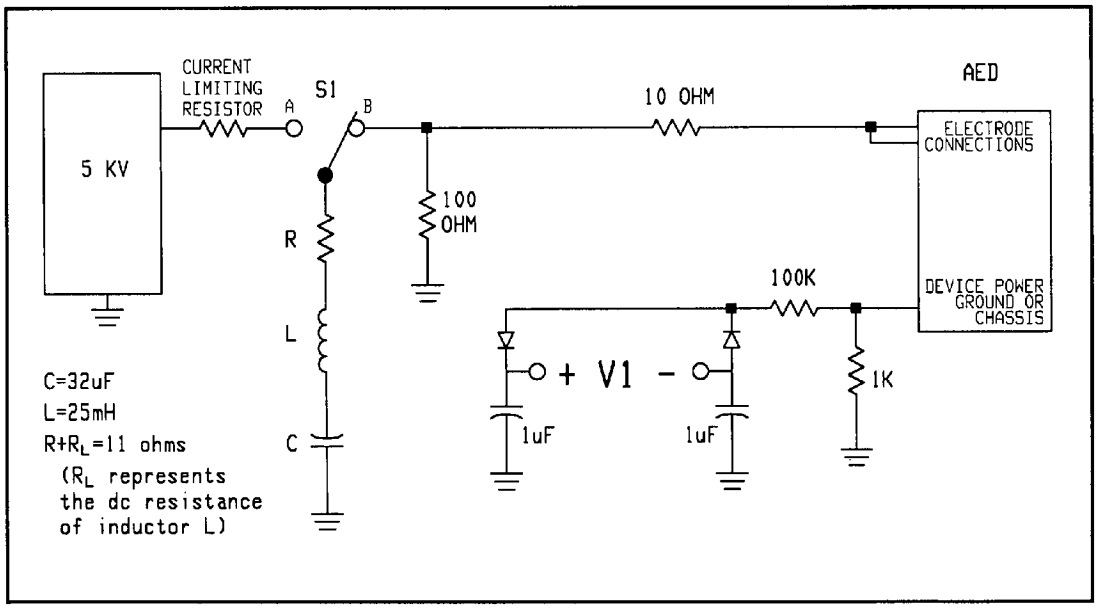

Figure 1.B—Test circuit for operator safety test (4.3.17.3)

4.3.19.2 AC large signal impedance

The large signal impedance of a pair of electrodes connected gel-to-gel in series with a 50-ohm test load can be determined by measuring the ratio of the peak voltages impressed across the electrodes and the test load due to an E_{MAX} discharge. This ratio should be less than or equal to 1:25.

4.3.19.3 Combined offset instability and noise

After a 1-minute stabilization period, the output voltage of the test circuit (derived from AAMI EC12, figure 1) shall not exceed 150 μV p-p over 5 minutes. Output voltage shall be measured with an instrument having a frequency response of 0.01 Hz to 1000 Hz and a minimum input impedance of 10 megohms.

4.3.19.4 Defibrillation overload recovery

The residual voltage of a pair of electrodes connected gel-to-gel in series with a 50-ohm test load can be determined by measuring the voltage impressed across the electrodes after three E_{MAX} discharges at 1-minute intervals. After the last discharge is delivered, the measured voltage shall not exceed 400mV at 4 seconds and 300 mV at 60 seconds.

4.3.19.5 Dielectric strength

For purposes of this test, a high potential (voltage adjustable) dc test source with integral ammeter is necessary. Connect the high potential lead to the nonconductive backing of the electrode (using aluminum foil if necessary). Connect the low potential lead of the test source to the active electrode area. Slowly adjust the output voltage amplitude of the test source to 1.5 times the maximum voltage occurring on the defibrillator energy storage capacitor. Maintain this voltage for 1 minute. The leakage current measured shall not exceed 250 μA.

4.3.19.6 DC offset voltage

The dc offset voltage shall be measured by connecting the electrodes gel-to-gel to form a circuit with a dc voltmeter having a minimum input impedance of 10 megohms and a resolution of 1 mV or better. The measuring instrument shall apply less than 10 nA of bias current to the electrodes under test. The measurement shall be made after a 1-minute stabilization period but before 1.5 minutes have elapsed.

4.3.19.7 Bias current tolerance

A 200-nA current shall be applied to a pair of electrodes connected gel-to-gel utilizing a current source consisting of at least a 2-V voltage source connected in series with an appropriate current setting resistor. The potential across the electrodes shall be monitored with a dc voltmeter having a minimum input impedance of 10 megohms, a resolution of 5 mV or better, and an input bias current less than 10 nA. The differential voltage across the electrodes should be measured at least once per hour over the period of observation. The initial offset voltage should be measured within 1 to 5 minutes after joining the electrodes and before bias current is applied. The offset voltage change caused by the applied bias current is then measured relative to the initial offset voltage. This voltage change shall not exceed 100 mV.

4.3.19.8 Electrode active area

The electrode active area is verified by measuring the dimensions and area of the electrode active contact surface.

4.3.19.9 Electrode adhesion and contact to patient

There is no reliable bench test for this characteristic. Testing is best performed in a controlled clinical environment (see rationale A.3.3.19.9).

4.3.19.10 Packaging and shelf life

Compliance with 3.3.19.10 can be verified by conducting the test of 4.3.19.1 through 4.3.19.9 at the end of the specified shelf life and temperature ranges provided.

4.3.19.11 Universal function electrodes

a) Compliance can be verified by comparison of the packaging description to the description of the functions performed within the operating instructions.

b) Compliance with the labeling and packaging information can be verified by inspection.

c) A pair of electrodes connected gel-to-gel, in series with a 50-ohm test load, shall be paced at the maximum pacing rate and maximum current output for 60 minutes. The electrode pair should be subjected to the performance tests of 4.3.19.

4.3.19.12 Cable length

Compliance with the cable length requirement is verified by measurement.

4.3.20 Event documentation

Compliance with the requirements is verified by inspection of the event documentation report.

4.3.21 Electromagnetic compatibility

AED and RCD are complex instruments because they use patient-coupled devices which markedly affect electromagnetic emissions and immunity. Equipment configurations for the tests will be determined by the manufacturer but the equipment shall be tested in a sufficient variety of configurations and operating modes that might be encountered in normal operation, so that the worst case may be determined and successfully tested. The pad electrode cables shall be tested both in an unterminated mode and in a patient simulated terminated mode.

Note that the requirements on EMC emissions are waived during the defibrillator charge/discharge cycle, for reasons stated in the rationale.

4.3.21.1 Electromagnetic emissions

4.3.21.1.1 Radiated and conducted EM emissions

The instrument shall comply with International Special Commission on Radio Interference (CISPR) 11, group 1, level B. The detailed test methods are outlined in CISPR 11 and CISPR 16.

The equipment shall be tested on all faces in all expected configurations and operating states. The ECG leads shall be tested in both an unterminated and a patient simulated (51-kohm resistor in parallel with 47 nF capacitor) terminated mode.

4.3.21.1.2 Magnetic field emissions

Use a gauss meter probe to verify that the instrument does not emit a magnetic field greater than .5 millitesla (5 gauss) at any point on the surface of the instrument under normal operating conditions.

4.3.21.2 Electromagnetic immunity

4.3.21.2.1 Immunity to radiated EM fields

Test methods and instruments specified in International Electrotechnical Commission (IEC) 801-3 apply.

All faces of the instrument shall be exposed to a modulated rf field with the following characteristics:

a) field strength: 3V/m (level 2) or 10V/m (level 3);

b) carrier frequency range: 26 MHz to 1 GHz;

c) 80 percent AM Modulation, at 1, 5, and 20 Hz.

For the level 2 test (3V/m) verify compliance with the requirements over the entire range of carrier and modulation frequencies.

For the level 3 test (10V/m) verify that there are no inadvertent discharges.

4.3.21.2.2 Immunity to conducted EM fields

The test methods and instruments specified in the current draft of IEC 801-6 apply.

An injected rf field as described in 3.3.21.2.2 shall be injected into the line cord. No inadvertent discharge or other unintentional change of state shall occur during this test.

4.3.21.2.3 Immunity to magnetic fields

The equipment is exposed on all faces to an external ac magnetic field with the following characteristics:

a) magnetic field strength: 10^{-4} tesla peak-to-peak;

b) frequency range: 47.5 Hz to 1520 Hz.

Verify that no inadvertent discharge or other unintentional change of state occurs.

4.3.21.2.4 Immunity to electrostatic discharge

The test method and instruments specified in IEC 801-2 apply. Verify that only transient loss of functionality occurs and the equipment resets without operator intervention.

4.3.21.2.5 Power and transients

a) First transients/burst—The test methods and instruments of IEC 801-4 apply.

b) Surge immunity—The test methods and instruments of the current draft of IEC 801-5 apply.

In both cases, verify that only transient loss of functionality occurs and the equipment resets without operator intervention.

4.4 External pacing

4.4.1 Pacing mode activation

Compliance with these requirements can be verified by inspection.

4.4.2 Pacing mode indicator

Compliance with this requirement can be verified by inspection.

4.4.3 Pacing delivery

a) Compliance with requirement 3.4.3.1 (a) and 3.4.3.2 (a) and (b) can be verified by inspection.

b) Compliance with requirement 3.4.3.1 (b) can be verified by performing the test described in 4.3.17.1, except that the external AED in figure 1.A is replaced by the pacer circuit.

c) Compliance with requirements 3.4.3.2 (c) can be verified by performing the tests of section 4.3.19.11 (c).

4.4.4 Pacing pulse shape and duration

a) Connect a 1000-ohm resistive test load and an oscilloscope between the pacing electrode connectors;

b) Activate the pacing mode;

c) The pacing pulse shape and duration shall fall within the limits specified for these parameters in the operating instructions.

4.4.5 Pacing pulse current

a) Perform steps (a) and (b) of 4.4.4;

b) The pacing pulse current shall fall within the limits specified for this parameter in the operating instructions. If a pacing current control is provided, the pacing pulse current will be measured at each setting for compliance;

c) Compliance with the labeling requirement for a pacing current control, if present, can be verified by inspection.

4.4.6 Pacing rate

a) Perform steps (a) and (b) of 4.4.4;

b) The pacing rate shall fall within the limits specified for this parameter in the operating instructions. If a pacing rate control is provided, the pacing rate will be measured at each setting for compliance. If the pacing rate control is continuously variable, measurement of the minimum and maximum settings and at least one other setting corresponding to the control's labeling will be performed;

c) Compliance with the labeling requirement for a pacing rate control, if present, can be verified by inspection.

4.4.7-4.4.8 Pacing protocol and sensitivity

a) Compliance with these requirements can be verified by comparison of actual device operation to the description of device operation provided in the operating instructions.

b) Compliance with the labeling requirement for a manual control, if present, can be verified by inspection.

4.5 Remote-control defibrillators

Test equipment and equipment accuracy shall be the same as for the AED as noted in 4.3.1.1 and 4.3.1.2. The following additional test equipment is required for the RCD:

a) ECG simulator;

b) telephone line simulator;

c) signal generator;

d) audio amplifier and speaker.

The following test procedure requirements are applicable to the RCD:

e) 4.3.1.3 Low temperature tests;

f) 4.3.2 (b), (c), (d) energy range;

g) 4.3.3 (a) – (h) energy accuracy;

h) 4.3.4 pulse shape and duration;

i) 4.3.5 (a) – (f) charge time;

j) 4.3.6 (a) – (d) battery capacity;

k) 4.3.7.2 (a) and (b) home/standby use;

l) 4.3.8 (a) – (d) energy loss rate;

m) 4.3.9 (a) – (d) automatic disarm;

n) 4.3.13 (a) and (b) low battery charge indicator;

o) 4.3.16 (a) – (f) disarm.

The following additional specific tests shall be performed for RCDs.

4.5.1 Audio quality

The audio quality speakerphone section of the RCD shall have a minimum passband of 300 Hz to 2,500 Hz. This test can be performed by passing audio sine waves of 100 Hz to 3,000 Hz from the microphone of the patient unit through the telephone simulator to the base station. The received waveform is measured at the speaker of the base station for linearity and volume. The same procedure is used by sending the signal from the base station for linearity and volume.

4.5.2 ECG quality

One mV sine waves are applied to the ECG input of the patient unit, transmitted via the simulated phone line (meeting the bandwidth requirements) to the base station and printed on the chart recorder. The passband of the patient unit shall be 1 Hz to 30 Hz minimum (-3dB points).

4.5.3 Telemetry of electrode impedance

The accuracy of the telemetry is checked by connecting a 0-ohm, 200-ohm, and 1,000-ohm load across the patient unit input. The base station telemetry reading shall be within ± 10 percent of the above values.

4.5.4 Compliance with referenced standards

Perform the tests prescribed in these standards.

4.5.5 Device labeling

Verify device labeling by inspection.

4.5.6 Base station requirements

Verify base station requirements by inspection.

4.5.7 Battery system

With fully charged batteries, the patient unit shall telemeter signals to and receive commands from the base station for at least 30 minutes.

4.5.8 Scheduled system testing

The person responsible for scheduled system testing shall follow the operating instructions and shall maintain a detailed, dated record of all tests performed.

4.5.9 Disconnect recognition and automatic reconnect capability of the device communication interface

The patient unit shall recognize telephone line disconnection and execute automatic reconnection. These functions are tested by interrupting the telephone line at the base station during operation and verifying that the patient unit and the base station recognize the interruption. The patient unit and base station shall attempt to reestablish contact within 30 seconds.

All control functions and keys shall be functionally tested and respond positively.

Annex A
(informative)

Rationale for the development and provisions of this standard

A.1 Introduction

This annex explains why the standard was developed and provides the rationale for the specific requirements in section 3.

This standard covers automatic external defibrillators (AEDs) that are capable of analyzing an electrocardiogram (ECG), identifying ventricular fibrillation (VF) and other ECG rhythms, and determining whether a shock is appropriate. The standard was developed by a committee with balanced representation of manufacturers and medical practitioners, and represents a consensus agreement by the committee of the provisions necessary and sufficient to give reasonable assurance of defibrillator efficacy and safety.

AEDs are relatively recent devices first used in the mid-1970s and commercially introduced in the late 1970s. The committee first discussed AEDs in 1984 and concluded at that time that the technology was so new and rapidly evolving that a standard was premature, though some recommendations or guidelines would be helpful to manufacturers and beneficial to users. Consequently, the committee developed a Technical Information Report, *Design, testing and reporting performance results of automatic external defibrillators*, published by AAMI in 1987. Subsequently, the committee recognized that AEDs enjoyed growing acceptance in the market, particularly for use by emergency medical services, and that the technology was maturing, so that a standard would now be appropriate. Development of the present standard was approved by the AAMI Standards Board in December 1988.

All AEDs currently on the market are indicated for use on adult patients, and are not indicated for use on infants or small children. Because cardiac arrest is extremely rare in infants or pediatric patients, the VF detection algorithms and the delivered energy levels (when automatically set or limited) are optimized for adults and may not be appropriate for small pediatric patients.

During the first ballot of the standard, comments were received from Mr. Prabodh Mathur, Vice President of Cardiac Science. These comments suggested several changes in section 3.3.18 (Rhythm recognition detector) that would be appropriate for the use of AEDs instead of Holter monitors for long-term ECG monitoring. The committee thought that this possible application of AEDs was novel, had merit, and might become accepted in the future. However, to our knowledge no AED is currently used for long-term monitoring and current AEDs have not been designed for that application. For long-term monitoring use it may be desirable to modify AED design in a number of ways not restricted to the rhythm recognition detector. The committee therefore decided to exclude long-term monitoring AEDs from the scope of the present standard, but to monitor the market and consider this application in a future revision of the standard if warranted by actual use.

A.2 Need for the standard

VF and sudden cardiac death are very frequent occurrences. They strike, without warning, several hundred thousand Americans every year and are one of the main causes of death in the United States and many other countries. VF is lethal unless promptly corrected, and defibrillation is the only effective, definitive therapy.

The time element in fibrillation is critical. Defibrillation has a high probability of success—and the patient a good prognosis for full recovery—if it occurs within 1 to 3 minutes of the onset of VF. As time in fibrillation lengthens, even when cardiopulmonary resuscitation (CPR) is administered, the probability of successful defibrillation declines steeply and the incidence of severe neurological deficit increases.

Early defibrillation can only be commonly accomplished if defibrillation is performed by a large number of

persons. This in turn can only be achieved if the training and skills required to defibrillate are minimal. This explains the growing interest in AEDs, which are capable of diagnosing VF and recommending defibrillation when appropriate, and can therefore be used by minimally trained operators (e.g., first responders, fire fighters, police, etc).

However, the very fact that large numbers of AEDs will be deployed and used by relatively unskilled operators for a lifesaving procedure makes it particularly important that AEDs be easy to use, clearly labeled, highly reliable, and meet high performance standards. This makes the need for a performance and safety standard particularly compelling for this type of device and provided the committee with the appropriate motivation and sense of urgency in developing this standard.

The presence of ECG analysis and VF detection algorithms as an essential component of an AED, and one critical to its efficacy and safety, posed some added difficulties: software and algorithms are more difficult to regulate and test in a standard than hardware or labeling. The committee attempted to address these difficult issues and propose reasonable responses.

A.3.1 Device labeling

The committee developed the requirements of 3.1 to assure that the device markings would remain legible under ordinary conditions of use and that important notices would be readily visible.

Existing federal regulations establish general requirements for the labeling of all medical devices. The provisions of 3.1 of this standard are intended to assure that certain specialized information, necessary for the safe and effective use of AEDs, will be included in device labeling.

A.3.1.1 Defibrillator

A.3.1.1.1 Identification

The display of device, battery, and battery charger identification data provides necessary information for use and reference, and assures traceability. This information would be of little value were it not readable and permanently attached to the instrument.

A.3.1.1.2 Defibrillator controls and indicators

The labeling of controls and indicators described in this section are based on those specified for manual defibrillators in 3.1.1.2 of ANSI/AAMI DF2—1989.

A.3.1.1.3 Defibrillator caution and warning notices

The caution and warning notices described in this section are based on those specified for manual defibrillators in 3.1.1.3 of ANSI/AAMI DF2—1989.

A.3.1.2 Self-adhesive electrodes for monitoring and defibrillation

The labeling on the electrode package allows convenient operator access to necessary instructions and other information when access to the device's operating instructions is either unlikely or impractical, e.g., during electrode application to a patient.

A.3.2 Operating instructions and maintenance manuals

No instrument can be operated properly without adequate instructions describing its use and controls. The information required in 3.2 is intended to ensure that sufficient instructions are available to the user for safe and effective operation and adequate maintenance of the device.

A.3.3 Essential requirements

A.3.3.1 Operating conditions

AEDs must perform under a wide range of environmental conditions. It is therefore reasonable to ask for disclosure in the manual of the range of environmental conditions within which the defibrillator has been tested and has performed successfully. In particular, AEDs designed for different applications may be required to perform over widely different temperature ranges, so it is appropriate to specify different temperature ranges for different products.

A.3.3.2 Energy range

The ANSI/AAMI DF2—1989 defibrillator standard reviews a number of studies of the appropriate range of defibrillation energy. The data used to support the 250 Joule (J) to 360 J energy range are generally valid and apply to general purpose AEDs. However, this standard also covers other types of AEDs for which design constraints and limitations in battery capacity result in offering a lower maximum energy level, and for which lower maximum energies have been shown to be successful.

A.3.3.3 Energy accuracy

This requirement was developed to ensure that the selected energy will, with reasonable accuracy, represent the delivered energy over the output range of the defibrillator and the impedance range of the patient circuit. The ± 15 percent tolerance also meets the desired objective of being small compared with the step increments normally used to increase energy during a defibrillation or cardioversion procedure.

The accuracy requirement for discharges into 25-ohm to 100-ohm loads is ± 5 J or ± 40 percent, whichever is greater. The allowed inaccuracy of 40 percent is undesirably large, but this large number is made necessary in the worst case to accommodate the ± 15 percent requirement for 50-ohm loads, plus an upper limit of 25 ohms for the internal resistance of the defibrillator patient circuit. Inductors with much lower internal resistance (for example, 10 ohms to 12 ohms) are available and are now commonly used. Such inductors will reduce the worst case inaccuracy to less than ± 30 percent. A possible increase from ± 5 J to ± 8 J permissible inaccuracy at low delivered energy was considered by the committee, but the increase was rejected because it would result in clinically excessive inaccuracies in the control of delivered energy at the low settings (for example, 10 J to 20 J) that are commonly used in internal or infant defibrillation.

A.3.3.4 Pulse shape and duration

A.3.3.4.1 Damped sinusoidal waveform

For many years, the damped sinusoidal waveforms often referred to as the Lown, Edmark, or Pantridge waveforms have been in widespread clinical use. The efficacy of these waveforms has been reaffirmed in recent clinical studies by Pantridge, et al. (Electrical requirements for ventricular fibrillation; *Brit. Med. J.,* 1975, vol. 2, p. 313–315), Campbell, et al. (Transthoracic ventricular defibrillation in adults; *Brit Med. J*., 1977, vol. 2, p. 1379–1381), and Gascho, et al. (Determinants of ventricular defibrillation in adults; *Circulation*, 1979a, vol. 60, p. 231–240; Energy levels and patient weight in ventricular defibrillation; *J. Amer. Med. Assn*., 1979b, vol. 242, p. 1380–1384).

It is well established that the pulse shape and duration of these waveforms change as a function of load resistance and that actual patient resistance in the clinical setting also varies. To specify the pulse shape and duration of these waveforms more completely, three values of load resistance—25, 50, and 100 ohms—were chosen. These values of resistance were chosen for convenience of testing and standardizing the waveform and may not correspond to the extremes or the mean values encountered in clinical practice.

The values for I_p, I_R, t_r, t_{50}, and t_{10} were determined in consultation with the manufacturers by overlaying waveforms from defibrillator models referenced in recent clinical studies (Pantridge, et al. [1975], Campbell, et al. [1977], Gascho, et al. [1979a]; see above) to determine an acceptable waveform envelope, and then adding a tolerance band to account for the 20 percent component variation consistent with the state of the art in the manufacture of damped sinusoidal waveform defibrillators.

A.3.3.4.2 Truncated exponential waveform

The family of truncated exponential waveforms often referred to as Schuder waveforms has been studied extensively with animals (Schuder, et al.; Transthoracic ventricular defibrillation with very high amplitude rectangular pulses; J. App. Physiol., 1976, vol. 2, no. 6, p. 1110–1114; and Transthoracic ventricular defibrillation in the 100-kg calf with untruncated and truncated exponential stimuli; *IEEE Trans. Biomed. Engr.,* 1980, vol. 27, no. 1, p. 37–43) but has not been as critically and extensively evaluated clinically as has the damped sinusoidal waveform. One published study (Anderson and Suelzer; The efficacy of trapezoidal waveforms for ventricular defibrillation; *Chest*, 1976, vol. 70, p. 298–300) has documented the clinical safety and efficacy of one such waveform. This waveform also changes pulse shape and duration as a function of patient resistance. For various values of patient resistance, the voltage to which the energy storage capacitor is charged remains relatively constant; the duration, and hence the final current, is adjusted to deliver approximately the energy that has been selected. To specify the pulse shape and duration of this waveform more completely, three values of load resistance—25, 50, and 100 ohms—were chosen. These values of resistance were chosen for convenience of testing and standardization of the waveform and may not correspond to the extremes or the mean values encountered in clinical practice.

The chosen values and range of I_p and t_F in the standard were compared with waveform specifications from the manufacturer of the defibrillator model referenced in a recent clinical study (Anderson and Suelzer, 1976; see above) and are consistent with the state of the art in the manufacture of truncated exponential waveform defibrillators. A tolerance band was added to account for a 20 percent component variation.

A.3.3.5 Charge time

The committee judged that a specific requirement for maximum charge time was appropriate. This specification was arrived at based on the requirement in 3.3.6 and on concerns for user interaction with the defibrillator, based on clinician input.

A.3.3.6 Battery capacity

The committee judged that a minimum battery capacity requirement was an essential part of this standard, and that the requirement should be different depending on the device application.

A.3.3.7 Battery shelf life

The committee judged that battery shelf life was a characteristic unique to the application of AEDs and that the required shelf life depended on the intended use of the device.

A.3.3.8 Energy loss rate

After a defibrillator is charged and ready for use, the operator may delay discharge for clinical reasons. The delay may range from minimal to the time (10 seconds to 30 seconds) when automatic disarm is activated. The requirement was developed to assure the user of the device that approximately the original energy selected still would be available even after maximum delay.

Because certain capacitors have a fast internal bleed-down rate, some defibrillators incorporate a "refresh" feature to maintain the stored energy charge with acceptable limits. Some devices maintain a ready status during this period and others inhibit discharge for a brief period of time (from about one-quarter of a second to 1 full second). Both methods are acceptable as long as the ready status of the defibrillator is accurately reflected by the charge indicator, the instrument returns to the ready state upon completion of refresh, and the instruction manual explains any restriction of operation during the refresh cycle.

A.3.3.9 Automatic disarm

This specification is a compromise similar to that used in the ANSI/AAMI DF2—1989 standard but also recognizes the different application of the AED. Due to use by less trained medical professionals or

nonmedical persons (e.g., first responders), the committee felt that a reduced automatic disarm time was appropriate.

A.3.3.10 Controls and indicators

The committee judged that for emergency equipment such as defibrillators, the number of controls and indicators with which the operator must contend to bring the equipment from an off condition to the desired charged state should be the minimum number consistent with good operational procedures. The standard therefore requires that controls be grouped functionally. This functional grouping of key controls was not intended to limit device design but to assure that where the controls and indicators described are provided, they are displayed as specified. This requirement is intended to minimize the probability of error and shorten the response time for effective operation when a user is confronted with an unfamiliar defibrillator in an emergency situation.

A.3.3.11 Energy level indicator

An indication of energy level is required to provide a credible indication to the operator that the defibrillator is functioning properly and is being charged to the desired energy level. The specification that the main scale be calibrated in terms of joules delivered to a purely resistive 50-ohm load was intended to enable a standardization in units that would be consistent for all types of defibrillators and energy delivery circuits.

A.3.3.12 Charge indicator

Because of the unique function and operational environment of defibrillators, the committee deemed it essential that the operator be aware of device status at all times. For this purpose, a positive visual indication shall be provided when the defibrillator is charged and ready to fire, and when it has been discharged. The requirement for a "charge" indicator, rather than for separate "discharged" or "charging" indicators, was intended to prevent confusion on the part of the operator when using an unfamiliar model in an emergency situation.

A.3.3.13 Low battery charge indicator

The ANSI/AAMI DF2—1989 standard recognizes the need for a low battery charge indicator and compromises in its final recommendation. The committee felt that due to the application and environmental conditions, a three-charge and discharge cycle following the low battery indicator was appropriate. The committee also felt that nonrechargeable batteries could be used in these devices and that the standard should allow their use.

A.3.3.14 Charge control

An AED can include a charge control, but many do not. The standard allows for both options. Studies have shown that, as used, AEDs operate appropriately with and without charge controls.

A.3.3.15 Discharge control

An AED can include a discharge control, but many do not. The standard allows for both options. Studies have shown that, as used, AEDs operate appropriately with and without discharge controls.

A.3.3.16 Disarm

The disarm requirement is intended to prevent inadvertent shocks from devices that have been "turned off." External voltages should be brought to zero and held there, regardless of operator action. Requiring disarm to occur when power is removed is intended to address the potential hazard that would be created by a double failure. Protection against multiple failures was not considered to be a minimum essential performance requirement and hence was not specified.

A.3.3.17 Defibrillator protection

A patient who is ECG monitored may develop VF, requiring emergency use of a defibrillator. The defibrillator operator may neglect to remove the small ECG monitoring electrodes and thus defibrillate a patient still connected to a cardiac monitor or an ECG. In fact he may choose to do that in order to use the cardiac monitor to examine the patient's ECG following defibrillation. Hence cardiac monitors should be "defibrillator protected" and should not shunt enough energy to cause defibrillation to fail.

The committee discussed at some length whether AEDs should be similarly "defibrillator protected" and "defibrillation compatible" (little or no energy shunting). It was finally decided to include defibrillator protection and energy shunting in the standard but to show these as disclosure rather than performance requirements for two reasons. The first reason is that the situation should not occur. If an AED fails to defibrillate and a second defibrillator is brought to the scene, it is urgently recommended that the pad electrodes of the first AED be removed before the second defibrillator is connected to the patient and discharged. It is almost inconceivable that this would not be done, since the large electrodes of the first AED would be in the position where the second defibrillator electrodes should be placed, and therefore the need to remove them should be obvious to the operator of the second defibrillator. The second reason is that the first AED will normally be in a monitoring mode, and monitoring circuits are normally (and correctly) protected from over-voltage by spark gaps or neon tubes. Upon discharge of the second defibrillator the spark gaps in the first AED will usually short circuit and the first AED will shunt most of the discharge energy away from the patient, thus preventing successful defibrillation.

An AED connected to a patient, therefore, should be disconnected before the patient is defibrillated by a second defibrillator. In the absence of a performance requirement, manufacturers are simply required to disclose whether or not their AEDs would be damaged by a discharge from the second defibrillator and whether they would shunt enough energy to prevent successful defibrillation (the latter being likely).

A.3.3.17.1 Recovery

A defibrillation-protected device will continue to function after exposure to the short-duration high voltages of a defibrillator discharge. The AED should be capable of recovering from the overload conditions within a few seconds after the defibrillator pulse, so as to give an indication of the presence or absence of the ECG and to be capable of functional rhythm recognition analysis, if it is needed for that purpose.

The ANSI/AAMI DF2—1989 defibrillator standard specifies a maximum selectable deliverable energy in the range of 250 J to 360 J. The energy and voltages that the AED sees as a result of a defibrillator discharge are dependent on the relative resistances of the human torso for the two paths, the relative placement of the electrodes of the AED and the second defibrillator, the skin-to-electrode resistances, and the effective impedance of the AED. The equivalent circuit is shown in figure A.1 (see next page), where the defibrillator is simulated by a capacitor (C) charged to voltage (V), and the stored energy (E) is given by $E = 1/2\ CV^2$.

For example, a capacitor of 32 μF charged to 5000 V will have a total stored energy of 400 J. This value has been proposed by the International Electrotechnical Commission (IEC) as a worst-case value for purposes of defining a defibrillator overload circuit. Using a total series resistance of 11 ohms (as indicated in figure 1.A), 360 J will be delivered into the test load, which corresponds to the maximum allowed by ANSI/AAMI DF2—1989.

A.3.3.17.2 Shunting

The human torso and skin-to-electrode resistance, under high energy discharge, varies over a wide range with a mean of 67 ohms and standard deviation of 36 ohms (hence m+SD = 103 ohms) in a study by Kerber, et al. (Transthoracic resistance in human defibrillation; *Circulation,* 1981, vol. 63, no. 3). The 100-ohm resistance specified for the tests of this standard fairly represents the worst-case voltage and power duration that the ECG device would see. The skin-to-electrode impedance (R_s) and the internal net impedance of the

AED under defibrillator overload (R_1) are highly variable.

The AED should not excessively shunt defibrillation currents from the patient. The result might be reduced efficacy of defibrillation, burning of the patient at the electrode contact sites, and reduced likelihood that the electrodes could continue sensing the ECG. These problems are minimized by allowing the device to absorb no more than 10 percent of the energy intended for delivery to the patient.

A.3.3.17.3 Operator safety

This requirement is intended to limit the hazard that may exist to an operator who is in contact with an AED that is connected to a patient being defibrillated by a second defibrillator. The requirement and the test circuit of figure 1.B are as in ANSI/AAMI EC11—1991, *Diagnostic electrocardiographic devices.* The measurement circuit can be understood as a charge integrator since, for any AED approaching the 100 μC limit, the voltage across R1 would be large relative to 1 volt.

The test method adopted in this standard sets R_S at 10 ohms. Use of this very low value for skin-to-electrode impedance puts a greater burden on the electrodes, both in terms of ability to absorb power and with respect to maximum voltage attained. Therefore, the test method of 4.3.17.1, utilizing 5000 V and 360 J, represents an overload that is more severe than would normally be encountered in actual practice and hence ensures that significant safety factors are built into the device.

A.3.3.18 Rhythm recognition detector

The committee felt that inclusion of a section on rhythm recognition was a key part of any standard on automatic defibrillators. The criteria chosen for inclusion in this section are based on a combination of inputs from clinicians on this committee (Drs. Crampton, Adgey, Cummins, Gessman, Kerber, Weaver; see also 2.1.2). The criteria are also based on current American Heart Association standards that apply for such devices and are also supported by Dr. Cummins' comparative evaluation of three AEDs published in the *Journal of American College of Cardiology* (Cummins, RO., Stalto, KR., Haggar, B., Kerber, RE., Schaeffer, S., and Brown, DD.; A New rhythm library for testing AEDs: Performance of 3 devices; *J. Am. Coll. Cardio*, 1988, vol. 11, p. 597-602). The performance of the rhythm recognition detector shall be subjected to bench and clinical testing with published results to permit clinical review and assessment. The primary requirement for AEDs is sensitive and specific detection of VF and this is the only mandatory requirement for all AEDs. In addition, it may be desirable that AEDs be capable of detecting VT with reasonable sensitivity and specificity. However, whether or not a shock is appropriate for a specific tachycardia must be determined. A simple rate criterion appears unreliable, and identification of "shockable" VT will generally require determination by the operator that the patient is pulseless and unconscious. Hence, to avoid operator confusion or uncertainty, it is essential that the manufacturer clearly state in labeling the rhythms that the AED detects and designates as shockable, as well as the criteria used to identify "shockable" VT.

A.3.3.19 Self-adhesive electrodes for monitoring and defibrillation, and optionally pacing

With conventional defibrillators, it has been customary to use separate pregelled ECG electrodes for monitoring and defibrillator paddle electrodes for defibrillation. The monitoring electrodes are not capable of effectively delivering a defibrillation shock and the paddle electrodes have only limited monitoring capability. Through the use of AEDs, it is very desirable to use self-adhesive pregelled disposable combination electrodes that perform well in the dual monitoring and defibrillation function. Recent studies also indicate that such combination electrodes may perform better than paddle electrodes for defibrillation. Hence, combination electrodes may become preferred for defibrillation. It is appropriate then in the defibrillator standard to outline a few requirements for such combination electrodes.

Considerations for performance requirements were given for both prime functions of the electrodes: ECG monitoring and defibrillation. Many of the ECG monitoring performance requirements were derived from

ANSI/AAMI EC12—1991, *Disposable ECG electrodes*, as functional parameters are applicable. Additional requirements are also provided relative to defibrillation performance (i.e., ac large signal impedance, dielectric strength, etc.).

It should be noted that the rationale for electrode requirements presumes possible use with a number of AEDs, similar to the rationale for pregelled ECG monitoring electrodes. However, self-adhesive combination electrodes are often designed for use with a specific device or family of devices. Therefore, system performance with the intended AED of use should be considered as the primary performance criteria.

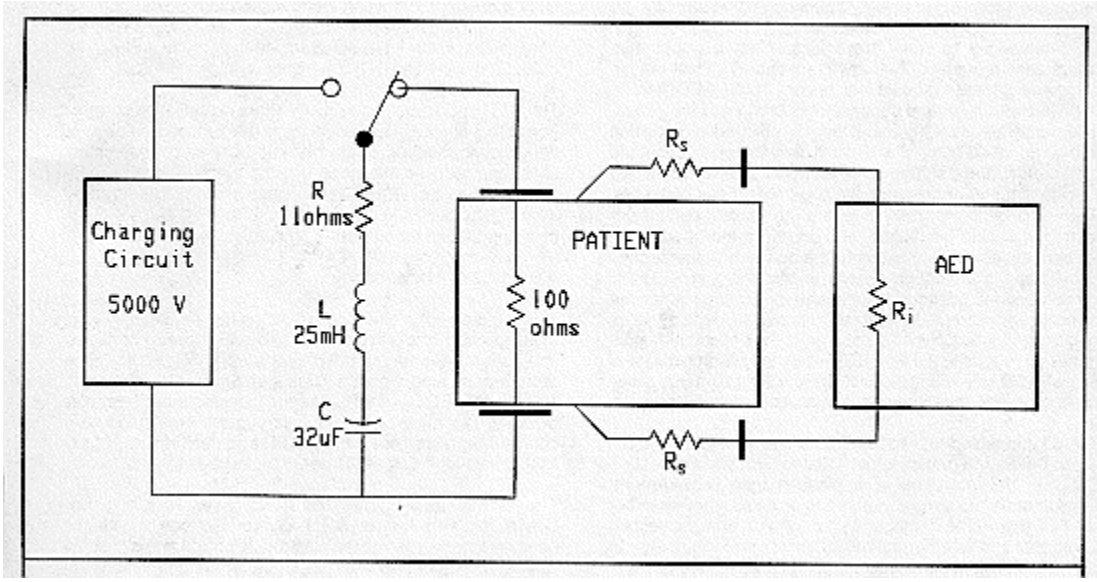

Figure A.1—Equivalent circuits for defibrillator discharge

A.3.3.19.1 AC small signal impedance

The rationale for this requirement was derived from the performance criteria in ANSI/AAMI EC12—1991.

A.3.3.19.2 AC large signal impedance

Impedance for self-adhesive electrodes may be higher than for standard hand-held electrode paddles used on manual defibrillators. This requirement provides a reasonable limit of impedance contributed by the electrode pair during defibrillation (less than 4 percent).

A.3.3.19.3 Combined offset instability and internal noise

The rationale for this requirement was derived from the performance criteria in ANSI/AAMI EC12—1991.

A.3.3.19.4 Defibrillation overload recovery

The fundamental rationale for this requirement is consistent with ANSI/AAMI EC12—1991 and ANSI/AAMI EC13—1993, *Cardiac monitors, heart rate meters, and alarms*. The requirement and test are stated in terms more directly applicable to AEDs; i.e., in terms of actual exposure to defibrillation energies rather than simulated dc offsets.

A.3.3.19.5 Dielectric strength

Similar to the rationale provided in ANSI/AAMI DF2—1989, this requirement gives reasonable assurance that proper insulation of the nonactive electrode part is provided.

A.3.3.19.6 DC offset voltage

The rationale for this requirement was derived from the performance criteria in ANSI/AAMI EC12—1991.

A.3.3.19.7 Bias current tolerance

The rationale for this requirement was derived from the performance criteria in ANSI/AAMI EC12—1991. This requirement is limited by the intended use of the AED electrodes and applies to long-term (hours) monitoring applications only.

A.3.3.19.8 Electrode active area

The ANSI/AAMI standard for conventional defibrillators requires a minimum active area of 50 cm^2 for paddle electrodes used for adult defibrillation, based on clinical studies of defibrillator efficacy for conventional paddle electrodes. However, there are indications that larger active areas are preferable and most defibrillators currently on the market use paddle electrodes with an active area of the order of 80 cm^2 for adult defibrillation.

AEDs use self-adhesive pad electrodes for defibrillation. The committee attempted to consider all available information. The following published studies were considered in reaching a decision:

a) Campbell, NPS., Webb, SW., Adgey, AAJ., and Pantridge, JF. Transthoracic ventricular defibrillation in adults. *British Medical Journal*, 1977, vol. 2, p. 1379-1381.

b) Dalzell, GWN. and Adgey, AAJ. Determinants of successful transthoracic defibrillation and outcome in ventricular fibrillation. *British Heart Journal*, 1991, vol. 65, p. 311-316.

c) Dalzell, GWN., Cunningham, SR., Anderson, J., and Adgey, AAJ. Electrode pad size, transthoracic impedance and success of external ventricular defibrillation. *American Journal of Cardiology*, 1989a, vol. 64, p. 741-744.

d) Dalzell, GWN., Magee, H., and Adgey, AAJ. Energy levels and transthoracic impedance in defibrillation (abstract). *Circulation*, 1988, vol. 78, II46.

e) Dalzell, GWN., Anderson, J., and Adgey, AAJ. Factors determining success and energy requirements for cardioversion of atrial fibrillation: Revised version. *Quarterly Journal of Medicine*, 1991, vol. 78, p. 85-95.

f) Dalzell, GWN., Cunningham, SR., Anderson, J., and ADGEY, AAJ. Initial experience with a microprocessor controlled current based defibrillator. *British Heart Journal*, 1989b, vol. 61, p. 502-505.

g) Kerber, RE., Charbonnier, F., et al. Energy, current, and success in defibrillation and cardioversion: Clinical studies using an automated impedance-based method of energy adjustment. *Circulation*, 1988, vol. 77, p. 1038-1046.

h) Kerber, RE. Guidelines for cardiopulmonary resuscitation and emergency cardiac care. *JAMA*, 1992, vol. 268, p. 2212.

i) Kerber, RE., et al. Self-adhesive preapplied electrode pads for defibrillation and cardioversion. *Journal of American College of Cardiology*, 1984, vol. 3, p. 815-820.

j) Stults, KR., Brown, DD., Cooley, F., and Kerber, RE. Self-adhesive monitor/defibrillation pads improve prehospital defibrillation success. *Annals of Emergency Medicine*, 1987, vol. 16, p. 872-877.

k) Wilson, RF., Sirna, S., White, CW., and Kerber, RE. Defibrillation of high-risk patients during coronary angiography using self-adhesive, preapplied electrode pads. *American Journal of Cardiology*, 1987, vol. 60, p. 380-382.

Additional unpublished data, particularly from Dr. Kerber, were also considered.

One published paper (Dalzell, 1989a) reported that transthoracic impedance (TTI) was excessively high (112 ohms ± 17 ohms) and defibrillation success for 200 J shocks was unacceptably low (31 percent first shock,

46 percent cumulative for two shocks) when two 8 cm diameter (active area 50 cm^2 each) pad electrodes were used. Impedance decreased to 92 ohms ± 22 ohms and defibrillation success increased to 63 percent/79 percent when unequal size pad electrodes were used, one 8 cm diameter and the other 12 cm diameter (110 cm^2 active area). A further improvement was noted when two 12 cm diameter pad electrodes were used, to 72 ohms ± 14 ohms and 82 percent/97 percent success. Based on this paper alone, 8x12 cm pad electrodes would seem to yield inferior results to hand-held paddle electrodes, even though a direct comparison was not made, and 12x12 cm pad electrodes would seem necessary to match the defibrillation success achieved earlier (Campbell, 1977) with paddle electrodes.

Dalzell (1989a) is the only published study of 8x8 cm pad electrodes and clearly shows their ineffectiveness. The committee considered all the published work on 8x12 cm pads, i.e., Dalzell (1989a and 1991a) and Stults. Stults, in the only published direct comparison of defibrillation success with 8x12 cm pad electrodes or with hand-held paddle electrodes in out-of-hospital defibrillation, clearly showed that the defibrillation success rate for 8x12 cm pads at 69 percent (cumulative for 2x200 J shocks) was far superior to that for paddle electrodes at 35 percent. Both published and unpublished studies by Kerber, some cited above, clearly show that inhospital values of impedance and defibrillation success rates are not statistically different for hand-held paddle electrodes or for 8x12 cm pad electrodes in either AA or AP positions. The AHA guidelines for CPR and ECC published in the *Journal of the American Medical Association* (JAMA), Oct. 1992, state: "Electrode size—For adult defibrillation, both hand-held paddle electrodes and self-adhesive pad electrodes 8 to 12 cm in diameter are most often used and perform well. Even smaller pads have been found effective during angiography."

The committee decided in 3.3.19.8 to require a minimum individual pad electrode area of 50 cm^2 and a minimum combined area of 150 cm^2 for the two pad electrodes.

The committee also agreed to review the issue of pad electrode size when the results of new studies become available.

A.3.3.19.9 Electrode adhesion and contact to patient

Good adhesion and electrical contact between the electrodes and the patient are essential for defibrillation efficacy. They shall be achieved for a variety of patient and environmental conditions, and maintained over an extended period of time prior to electrode use.

Test and evaluation experience indicates, however, that a bench test for evaluating adhesion performance is not practical or reliable. Proper performance assessment is best done in a controlled clinical environment. This recomendation is consistent with AAMI Electrocardiograph Committee conclusions documented in ANSI/AAMI EC12—1991.

A.3.3.19.10 Packaging and shelf life

The requirement of 3.3.19.10 is necessary to ensure that the electrode remains reliable under ordinary conditions of storage. Temperature ranges provided are felt to be reasonable estimations of typical storage conditions. Exceptions should be so noted in the labeling for the electrodes.

A.3.3.19.11 Universal function electrodes

An AED may incorporate external transcutaneous pacing as either a distinct treatment mode from the defibrillation treatment or as part of a combined defibrillation/pacing/monitoring operation. Since no general performance standards currently exist on a combination pacing/defibrillation/monitoring electrode, the requirements of 3.3.19.11 define the basic minimum controls necessary to ensure safe and reliable operation.

A.3.3.19.12 Cable length

A minimum cable length of 2 m (80 in) was specified for those units requiring cables, to ensure that the user

has adequate cable for most purposes. Although it was recognized that a minimum cable length of 3 m (10 ft) might be more useful in some circumstances, it was felt that a 3-m cable would be rather cumbersome for some mobile applications and hence was not specified as a minimum requirement.

A.3.3.20 Event documentation

Persons who use AEDs will typically have minimal training in medical emergencies. Their general use of AEDs should be authorized and supervised by a medical control authority. They may possess limited ability to interpret ECG rhythms or to recall specific actions they performed during a resuscitation effort. Automated event documentation is therefore a necessary feature of AEDs that will allow the medical control authority to review retrospectively in detail each clinical use of an AED and to formulate better instructions and training programs.

The specific requirements on information content are based on the AHA medical/scientific statement, "Recommended guidelines for uniform reporting of data from out-of-hospital cardiac arrest: The Utstein style. A statement for health professionals from a task force of the American Heart Association, the European Resuscitation Council, the Heart and Stroke Foundation of Canada, and the Australian Resuscitation Council," by Richard Cummins and Douglas Chamberlain, Cochairmen. The statement was published in *Circulation*, August 1991, vol. 84, no. 2, p. 968-975.

A.3.3.20.1 Purpose

A.3.3.20.2 Methods of event documentation

Event documentation may be achieved by different media such as medical tape cassettes or solid-state memory, at the choice of the manufacturer. However, it should be realized that certain important characteristics of emergency field performance can only be evaluated with a continuous voice recording. Hence, in some settings in which AEDs are used, medical control authorities may determine that continuous voice recordings are essential for adequate medical control.

A.3.3.20.3 Information content of event documentation

It is anticipated that most users of AEDs will be minimally trained for emergency responses. Many of the recommended items of event documentation permit detailed recordkeeping by the person responsible for medical control. These items permit assessment of specific device performance, the clinical performance of the operators, and the final clinical outcomes. Successful use of an AED in terms of clinical outcomes requires rapid attachment of the device, followed by rapid assessment of the rhythm, charging of the device, and delivery of the shock. The items recommended for inclusion in event documentation allow retrospective review to identify problems in speed of operation, sequencing of steps, and rhythm interpretation. Problems identified in retrospective event review can be addressed through quality improvement methods such as continuing education and retraining. Event documentation should not be misinterpreted as a means of discovery of negligence in prehospital care but should be emphasized as a means of quality improvement.

A.3.3.21 Electromagnetic compatibility (EMC) requirements

With the proliferation of digital and computer instruments working at close range in the hospital, for instance in the intensive care unit (ICU) or in the operating room (OR), there are a growing number of instances where one instrument emits radiation which interferes with the performance of another instrument. EMC must therefore be considered, in the expectation that compliance with EMC standards, on both emission and immunity, will minimize detrimental interference between instruments.

EMC performance and validation tests are very complex and require sophisticated instrumentation. It is not practical to make the AED standard a stand-alone document by including all the pertinent information, particularly concerning test methods and instrumentation. Instead, we reference a number of IEC documents

which specify in detail the appropriate EMC test methods and instruments. Two of these documents are still in draft stage; hence are subject to possible change. However, drafts of these documents are available and are routinely used by development and test engineers; it is therefore reasonable to reference and use these documents, and we have no alternative at this time. Clearly, if the final documents differ from the current drafts, the committee will have to examine the impact on the present standard and consider possible revisions.

The standard addresses two complementary subjects: emission, i.e., the intensity and characteristics of EM radiation emitted or conducted by an operating device, and immunity, i.e., the ability of an instrument to perform satisfactorily while exposed to external EM radiation. The standard sets maximum levels on EM emission and defines the levels of external radiation that the device shall tolerate and still perform satisfactorily.

The maximum levels of emission stated in the general standards have been adjusted to the specific device considered, i.e., AED or RCD, and require a design effort by the manufacturer. While the emission levels are achievable with good design, the levels may be different for different operating modes, and may be waived when they cannot be achieved during certain operating modes.

The IEC collateral standard 601-1-2 on EMC in medical devices recognizes that measurement and control of EMC is particularly difficult for patient-coupled devices, such as AEDs, where the patient cables act as antennas which both emit and receive rf signals, with an antenna gain which depends on the layout of the patient cables. The IEC standard makes allowance for this situation by providing limited exemptions from the immunity requirements. These exemptions are extended to the present standard, on condition that the reduced immunity levels be measured and disclosed by the manufacturer.

For immunity measurements, the cables and self-adhesive electrodes (pads) shall be terminated in a load which reasonably simulates a patient being monitored. For the small area monitoring electrodes used in cardiology, ambulatory monitoring, or conventional defibrillation, a parallel combination of 51 kohm and 47 nF is normally used to simulate the patient. Considering the much larger active area of pads (150cm^2 total) used in AEDs the load simulating the patient should have a much smaller R and a much larger C. Values of 1 kohm and 1μF are recommended, even though the optimum values are not precisely known and may vary from one situation to another.

For the specific case of AEDs, we can distinguish four operating modes:

a) monitoring;

b) charging to defibrillate;

c) discharging;

d) connected, directly or indirectly, to mains power.

All EMC emission requirements are waived during the discharge. This waiver is obviously needed because a full energy discharge, with paddles or pads connected to the patient through 2 to 3 meters of cable, inevitably radiates high fields. The waiver during the charge cycle reflects a different condition. The IEC 601-1-2 EMC standard allows a 20 dB increase in emission level during a brief EM disturbance or "click." Manufacturers strive to minimize EM emissions during the charge cycle and we believe that they would easily meet a requirement based on the click allowance. However, it is not practical to measure emission levels over a wide range of frequencies and at multiple locations during the very short duration of a charge cycle (1-4 records for some defibrillators). Hence, we decided not to include a requirement (for maximum emitted rf or magnetic field) that could not be verified by test.

Similarly, the EM levels stated in the immunity subsection represent a compromise between AED design state-of-the-art and the almost infinite variety of EM environments that a portable device may encounter.

The general documents quoted in reference (CISPR, IEC) have standardized performance on approximately four levels, which represent increasingly harsh environments. Level 2 environments are commonly encountered; hence full immunity to level 2 fields is required. Level 3 environments are rare but may be found (e.g., in the OR or near power lines, etc.) and it is important to indicate the performance of the instrument in a level 3 environment.

Whereas it is relatively straightforward to measure and define the performance and immunity of a conventional defibrillator in the various environmental levels, an essential part of an AED is the ECG analysis and VF detection algorithm. Clearly, a very strong rf field will inject noise in the recorded ECG. The intensity and frequency characteristics of the induced noise vary over a very wide range and it is impossible to state how the sensitivity and specificity of the VF detection algorithm are affected by noise across the whole range of amplitude and spectral characteristics. Hence, manufacturers are expected to do careful signal conditioning and to develop algorithms that are as immune as possible to environment-induced distortions of the ECG signal. For EMC requirements it is a generally accepted practice to define standardized and progressively more severe EM environments and specify the device response to these standardized environments. There is an almost infinite variety of field environments in which AEDs may have to operate. As manufacturers identify likely environments which differ from the standardized environments covered in this standard, they are asked to test their devices in these environments, seek to achieve the highest possible immunity, and disclose any observed degradation in performance, so that the user will have appropriate warnings.

Finally, EMC is a rapidly developing subject for which standards are evolving. This section of the AED standard is likely to be revised and improved in the future.

A.3.4 External pacing

An AED may incorporate external pacing either as a distinct pacing treatment mode separate from the defibrillation treatment mode, or as part of a combined defibrillation/pacing operating protocol. Since no general performance standards currently exist on external pacing, the requirements of 3.4 define the basic controls and pacing pulse criteria typically found on currently available external pacemakers. Specific limits have not been defined for the requirements in 3.4 due to existing legal concerns and further development in this area.

A.3.5 Remote-control defibrillators

RCDs have much in common with manual defibrillators, and some features in common with AEDs. The unique characteristic of RCDs is that they establish a link between the remote medical personnel and the ultimate user—the patient. This link is designed to make possible observation, communication, and intervention including synchronized cardioversion and defibrillation. These basic characteristics justify section 3.5.4 in which the RCD is required to comply with the standards promulgated for manual defibrillators and for AEDs.

Since RCDs rely heavily on a communications link, 3.5 and 3.5.9.1 deal very extensively with the characteristics and requirements of the link. Another distinctive feature of the RCD is that it functions only as part of a two-unit system comprised of the patient unit in the home or workplace and the base station in a medical facility under medical supervision. Thus the standard includes requirements for the base station. Furthermore, information and training should be provided for base station operators and for bystanders and patients. Because of the above characteristics, periodic tests shall be conducted on the entire range of functions, including communications and commands between the patient unit and the base station, in order to maintain safe, reliable performance that ensures the safety of the patient under the worst-condition scenario. Section 3.5.9.1 requires instructions to the bystander to call the local emergency phone number in case of failure to communicate with the base station after an appropriate interval.

Reliable and accurate communication between the patient unit and the base station is essential for safe and

effective RCD operation. In particular, the communication link shall be protected so that the defibrillator cannot charge or discharge due to any single component failure or due to random noise. There may be several methods for achieving the necessary protection and the standard does not mandate a particular design. However, by way of example, the presently available RCD uses the dual tone multiple frequency (DTMF) system. The DTMF system uses the addition of two dissimilar frequencies to produce a tone that is unique to a given digit. During the charge command (1 button) or discharge command (2 buttons), a four-digit command is sent from the base station to the patient unit. The DTMF decoder in the patient unit decodes the tones and produces the necessary output signals only when the correct combination of tones is present for a predetermined period of time in the correct order. A number of additional fail-safe codings are built in. These fail-safe protections are extended to all critical functions such as energy select or dump.

Lesser functions such as calibration, voice control commands, etc., employ some of the above protection techniques depending upon how critical the function is.

The system described above has proved 100 percent effective in bench tests, in site tests, and in use in the field over the past several years. Future systems might employ different techniques, but the objective of safe function should be the same.

A.3.5.3 Measurement of patient and electrode impedance

Remote defibrillation with an RCD is under the remote control of a physician at the base unit. The physician at the base unit shall ensure that electrodes are correctly placed and in good contact with the patient so that defibrillation has a chance of success. Measuring TTI is the best method for assessing good electrode placement and contact, hence it is essential that the RCD be designed to measure TTI and transmit the result to the base unit by telemetry. Predischarge measurement of TTI has become standard on several commercially available defibrillators which all use similar circuits for that purpose and meet the accuracy requirement. The decision to defibrillate immediately, or to work further on technique before attempting to defibrillate, should be made by the physician, based on the value of TTI. Hence the physician needs the TTI value to be displayed, rather than a qualitative indication of TTI being normal, too low, or too high.

Annex B
(Informative)

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