

**American
National
Standard**

ANSI/AAMI DF39:1993

**Automatic external defibrillators
and remote-control defibrillators**

AAMI

Association for the
Advancement of Medical
Instrumentation



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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 in-hospital 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.

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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, μ A,	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, μ F, 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 oropharyngeal 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.