

American National Standard

ANSI/AAMI DF2:1996

Cardiac defibrillator devices

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Association for the
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DF2 Cardiac defibrillator devices

American National Standard

ANSI/AAMI DF2—1996 (Revision of ANSI/AAMI DF2—1989)

Cardiac defibrillator devices

Developed by

Association for the Advancement of Medical Instrumentation

Approved 29 April 1996 by

American National Standards Institute, Inc.

Abstract:

This standard provides minimum labeling, performance, and safety requirements for cardiac defibrillator devices. Also included are referee test methods by which compliance can be verified.

Keywords:

cardioversion, defibrillation, synchronized cardioversion, ventricular fibrillation

Committee representation

Association for the Advancement of Medical Instrumentation

Defibrillator Committee

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

At the time this document was approved, the **AAMI Defibrillator Committee** had the following members:

Cochairs: Francis Charbonnier, PhD

Richard Kerber, MD

Members: A. A. J. Adgey, MD, Royal Victoria Hospital

Laura Aguilar, 3M Company

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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 AAMI Defibrillator Committee. 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 for cardiac defibrillator devices.

NOTE—The safety and performance criteria defined in this standard are intended for use in design qualification or "type" evaluation by the device manufacturer; the standard is not intended for use in routine inspection or comprehensive performance evaluation of individual devices. 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 on selectable energy that are intended to provide reasonable assurance of successful defibrillation of patients in ventricular fibrillation.

The standard primarily is written to provide defibrillator manufacturers with 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 a 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 with applications 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 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 could 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 part of the American National Standard, *Cardiac defibrillator devices* (ANSI/AAMI DF2—1996), but it does provide important information about its development and intended use.

Cardiac defibrillator devices

1 Scope

1.1 General

A cardioverter-defibrillator is an electronic apparatus used to terminate cardiac tachyarrhythmias, including ventricular fibrillation, by the application of electrodes to deliver a brief electric shock to the heart. This standard establishes minimum performance and safety requirements for all conventional hospital or mobile rescue cardiac defibrillators.

Special features, such as the capability for synchronized discharge for the reversion of atrial fibrillation or ventricular tachycardia (synchronized cardioversion), are addressed but are optional in nature and are not to be construed as required for all defibrillators. Where such features are provided, however, they shall comply with the applicable requirements of this standard.

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 not intended for use by end users of the device.

This 1996 standard replaces the 1989 edition (ANSI/AAMI DF2-1989). Some requirements have been modified, and new ones have been added. The requirements in this document, as well as any subsequent

revisions, are not retroactive.

1.2 Inclusions

This standard specifically addresses

- a) conventional defibrillators for use in hospitals, clinics, physicians' offices, and emergency medical services;
- b) defibrillators with an integrated cardiac monitor or attached to an external cardiac monitor-defibrillator;
- c) defibrillators that are line-powered or battery-powered;
- d) defibrillators with special controls and circuitry intended for synchronized cardioversion, i.e., the treatment of ventricular tachycardia or atrial fibrillation by means of an electric shock synchronized with ventricular contractions;
- e) external transcutaneous pacers that are a part of a defibrillator-pacer instrument;
- f) self-adhesive single- or multiple-function (defibrillation/monitoring/pacing) electrodes.

1.3 Exclusions

This standard does not cover:

- a) automatic or advisory external defibrillators that contain rhythm detectors and shock-decision algorithms. These devices are covered more completely by a separate standard, ANSI/AAMI [DF39—1993](#);
- b) stand-alone pacemakers, implantable or external transcutaneous;
- c) automatic implantable cardioverter-defibrillators, with or without pacing (ICDs).

1.4 Abbreviations and acronyms

A, mA,	Ampere, milliampere, microampere,
μA, nA	nanoampere (units of electrical current)
μA p-p	microampere peak-to-peak
ANSI	American National Standards Institute
CISPR	International Special Committee on Radio Interference
ECG	Electrocardiogram
EMAX	Maximum delivered energy
EMC	Electromagnetic compatibility
F, μF, nF	Farad, microfarad, nanofarad (units of capacitance)
hPa	HectoPascal (unit of atmospheric pressure)
Hz, kHz, MHz, GHz	Hertz, kilohertz, megahertz, gigahertz (units of frequency)
IEC	International Electrotechnical Commission
Ω, kΩ, MΩ	Ohm, kilohm, megohm (units of resistance)

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

The following documents contain provisions that, 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 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Automatic external defibrillators and remote control defibrillators*. ANSI/AAMI DF39—1993. Arlington (VA): AAMI, 1993. American National Standard.

2.2 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Biological evaluation of medical devices—Part 1: Guidance on selection of tests*. ANSI/AAMI 10993.1:1994. Arlington (VA): AAMI, 1994. American National Standard.

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

2.4 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Safe current limits for electromedical apparatus*. ANSI/AAMI ES1—1993. Arlington (VA): AAMI, 1993. American National Standard.

2.5 INTERNATIONAL ELECTROTECHNICAL COMMISSION. *Electromagnetic compatibility for industrial process measurement and control equipment*, IEC 1000-4 series. Geneva, Switzerland: IEC. (Available from ANSI)

- IEC 1000-4-2:1994 Electrostatic discharges requirements
- IEC 1000-4-3:1993 (ENV 50140) Immunity to radiated radio frequency electromagnetic fields
- IEC 1000-4-4:1994 Electrical fast transient burst requirements
- IEC 1000-4-5:1995 (ENV 50142) Voltage surge immunity requirements
- IEC 1000-4-6:1993 (ENV 50141) Currently document 77B/144/DIS, Immunity to conducted disturbances induced by rf fields (draft International Standard)
- IEC 1000-4-8:1993 Power-frequency H field immunity

2.6 INTERNATIONAL ELECTROTECHNICAL COMMISSION. *Medical electrical equipment ¾Part 2: Collateral standard: Electromagnetic compatibility: Requirements and test*. (IEC 601-1-2). Geneva, Switzerland: IEC, 1993. (Available from ANSI)

2.7 INTERNATIONAL ELECTROTECHNICAL COMMISSION. *Degrees of protection provided by enclosures (IP Codes)*. (IEC 529). Geneva: IEC, 1989.

2.8 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)

2.9 UNITED STATES DEPARTMENT OF DEFENSE. *Military standard environmental test methods and engineering guidelines.* MIL-STD-810E, 1989.

3 Definitions

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

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

3.2 external defibrillation: 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.

3.3 external transcutaneous pacer: 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.

3.4 pacing: Application of moderate-energy pulses of very short duration 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.

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

3.6 synchronized cardioversion: Timed application of a high-energy, short-duration electrical discharge to the heart to terminate arrhythmias that 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).

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

3.8 ventricular fibrillation: 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 usually is self-sustaining and can be terminated only by a strong electrical discharge (defibrillation).

4 Requirements

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

4.1 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.

4.1.1 Defibrillator labeling—Control indicators—Cautionary warning notices

Identification and electrical rating markings shall be readily visible on the defibrillator and the battery charger. 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 (if applicable);
- e) line (mains) voltage range;
- f) peak line current (the average over the 2 seconds immediately following initiation of charge for maximum energy select);
- g) line frequency range;
- h) 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 (if applicable).

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, if present, shall be labeled SYNC for synchronized cardioversion and optionally labeled DEFIB for ventricular defibrillation. Any additional mode selections, if provided, shall be designated by distinctively different titles that 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.

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 be readily visible during any approach to attempt servicing.
- c) "DANGER-Possible explosion hazard if used in the presence of concentrated oxygen."

4.1.2 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.

4.1.3 Self-adhesive electrode labeling

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.

4.1.4 Pacer labeling

4.1.4.1 Pacing controls and indicators

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

- a) If pacing is manually controlled by the operator, the control used to activate pacing will be labeled PACING ON/OFF or equivalent.
- b) If operator selection is provided, the control that selects the pacing pulse current shall be labeled OUTPUT (milliamperes (mA)) or equivalent with the selected current level indicated.
- c) 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 (pulse per minute (ppm)) or equivalent with the selected rate indicated.
- d) If the unit has the capability of switching between demand and continuous mode pacing, the mode selection control shall be labeled PACER MODE or equivalent. Additionally, the mode selected shall be clearly presented via either the information display (e.g., CRT or LCD) or indicator light; or, if the mode-selector switch has multiple positions, the switch positions shall be clearly labeled to indicate the demand and continuous mode positions. In cases where an information display is present, it is preferable that the mode be presented on the display.
- e) Indication shall be provided when the pacing mode is operative.

4.2 Operating instructions and maintenance manuals

4.2.1 Defibrillator operating instructions and maintenance manuals

An instruction manual shall be provided with each defibrillator. The instruction manual shall include, as 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) the operating conditions for which the device is qualified (indoor use, indoor/outdoor/ground-transportation use, indoor/outdoor/ground-transportation/air-transportation use);
- c) specification of accessory components required for system operation, such as electrodes, patient connection cables (if detachable), battery, and battery charger (if applicable);
- d) specific instructions for the defibrillation procedures, including safety considerations in the intended use and cautions against misuse;
- e) if the defibrillator is able to perform synchronized cardioversion, specific instructions for the synchronized cardioversion procedure, including safety considerations related to obtaining a quality ECG for R-wave synchronization and related to the operating mode of the defibrillator following a synchronized shock (either remain in synchronized shock mode or return to normal defibrillation mode);
- f) instructions on care, preventive maintenance, cleaning, periodic check, and periodic bench testing of the equipment; this applies particularly to the battery system, which requires special care to maintain reliable operation;
- g) description of the range of other environmental conditions (for example, humidity, pressure, shock and vibration, and electromagnetic radiation) over which the defibrillator was tested and performs successfully, and optional description of the electromagnetic radiation emitted by the defibrillator during charge and discharge, with measurements if available, because such radiation might cause nearby instruments or computers to malfunction;
- h) description of adverse conditions (e.g., low battery, electromagnetic radiation, ECG artifact, pacemaker spikes, defibrillation recovery, or other environmental noise conditions) that might degrade the defibrillator operation;
- i) specific instructions for operating the defibrillator using its battery system, including the steps for recharging the battery system.

The instructions of 4.2.1(d) shall include a specific warning on the potential hazards of open and shorted paddle electrode discharges to the operator and possibly to the equipment. In addition, a notice shall be placed in the instruction manual specifying the maximum time that 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 also shall include, where applicable, component replacement procedures, schematic circuit diagrams, and the address of one or more authorized repair facilities.

4.2.2 Pacer-specific operating instructions and maintenance manuals

All requirements of 4.2.1 not applicable specifically to defibrillation functions apply to pacer functions as well. The instruction manual shall include at least the following pacer-specific information:

- a) specific instructions for pacing procedures, including safety considerations in the intended use and cautions against misuse;
- b) electrode placement and connection;
- c) the protocol for setting pacing pulse amplitude and rate and determination of capture;

d) the pacing pulse shape (waveform) and duration.

4.3 Essential requirements

4.3.1 Operating conditions

Based on the specified use environment, defibrillators shall operate successfully and meet all performance requirements of this standard, when subjected to the environmental conditions listed in the table below, unless otherwise stated.

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

Condition	Indoor Use Only ⁽¹⁾	General Use and Ground Transport	Air/Helicopter Transport ⁽²⁾
1) Temperature	15° - 35° C	0° - 45° C	0° - 45° C
2) Humidity, non-condensing ⁽³⁾	30% - 95% RH @ 20° C	30% - 95% RH @ 20° C	30% - 95% RH @ 20° C
3) Atmospheric Pressure	860 - 1060 hPa	860 - 1060 hPa	700 - 1060 hPa
4) Vibration	MIL-STD-810E Method 514.4, Category 1 (Basic Transportation) ⁽⁴⁾	MIL-STD-810E Method 514.4, Category 1 (Basic Transportation) ⁽⁵⁾	MIL-STD-810E Method 514.4, Category 4 (Propeller Aircraft), 5 (Jet Aircraft), 6 (Helicopter), and/or 10 (Integrity Test for Helicopters) ⁽⁶⁾
5) Shock/Drop	MIL-STD-810E Method 516.4, Procedure I (Functional Shock) ⁽⁷⁾	MIL-STD-810E Method 516.4, Procedure I (Functional Shock) ⁽⁷⁾	MIL-STD-810E Method 516.4, Procedure I (Functional Shock) ⁽⁷⁾
6) Enclosure Protection, Solid Foreign Object Ingress	IEC 529, Level 2 (IP2x) (12.5 mm spheres & test finger)	IEC 529, Level 2 (IP2x) (12.5 mm spheres & test finger)	IEC 529, Level 2 (IP2x) (12.5 mm spheres & test finger)
7) Enclosure, Protection, Water Ingress	IEC 529, Level 1 (IPx1) (vertically falling water drops)	IEC 529, Level 3 (IPx3) (spraying water)	IEC 529, Level 3 (IPx3) (spraying water)

NOTES—

1. These requirements apply to defibrillators that are designed and labeled for indoor use only.
2. These requirements apply to defibrillators that are designed and labeled for air/helicopter transport use in addition to general use and ground transport use.
3. Specific components may be exempted from operation above 80% RH (e.g., the recorder because of the inability of recorder paper to perform at these high humidity levels) if the exception is clearly stated in the user documentation. However, the requirements relating to the defibrillator's ability to deliver a shock must be met.
4. Random vibration as specified in figure 514.4-1 for 10 minutes in each of 3 axes, 30 minutes total test time.
5. Random vibration as specified in figure 514.4-1 for 60 minutes in each of 3 axes, 3 hours total test time.

6. The manufacturer shall clearly disclose in the user documentation the test category and specifics of the test selected, including test duration. For example, several tests are specific to defibrillator mounting location and type of aircraft.

7. Three shocks in each direction in each of 3 axes, 18 shocks total (if the required peak acceleration is exceeded in both directions along an axis with a single shock, 9 shocks total). Each shock shall exceed 40 g peak acceleration over an effective transient duration of 6-9 ms.

4.3.2 Energy range

The maximum selectable delivered energy of the defibrillator shall lie in the range of 250 to 360 joules inclusive, hereafter termed E_{MAX} . The defibrillator shall provide a selection of energy outputs. For defibrillators not having the capability for synchronized discharge, this selection shall include at least 10 joules or less (but not 0), E_{MAX} , and 6 intermediate values. For defibrillators capable of synchronized discharge, the selection shall include at least 5 joules or less (but not 0), E_{MAX} , and 6 intermediate values. For internal paddle electrodes, the maximum selectable delivered energy shall be 50 joules, and a caution notice shall be placed on the internal paddle electrodes or defibrillator recommending that lower energies be used for internal defibrillation because of possible cardiac damage from higher energies.

Table 1 ¾ Specifications for damped sinusoidal output waveforms

Load Resistance				
Waveform Parameter	25 Ohms	50 Ohms	100 Ohms	125 Ohms
I_p (amperes)	$96\alpha \geq I_p \geq 55\alpha$	$66\alpha \geq I_p \geq 45\alpha$	$46\alpha \geq I_p \geq 25.1\alpha$	$46\alpha \geq I_p \geq 20\alpha$
$ I_R $ (amperes)	$ I_R \leq 0.40 I_p$	$ I_R \leq 0.40 I_p$	$ I_R \leq 0.40 I_p$	$ I_R \leq 0.40 I_p$
$ I_{20 \text{ max}} $ (amperes)	$ I_{20 \text{ max}} \leq 0.01 I_p$	$ I_{20 \text{ max}} \leq 0.015 I_p$	$ I_{20 \text{ max}} \leq 0.04 I_p$	$ I_{20 \text{ max}} \leq 0.075 I_p$
t_r (ms)	$1.60 \geq t_r \geq 0.50$	$1.42 \geq t_r \geq 0.40$	$1.25 \geq t_r \geq 0.30$	$1.25 \geq t_r \geq 0.20$
t_{50} (ms)	$4.60 \geq t_{50} \geq 2.00$	$4.17 \geq t_{50} \geq 2.10$	$6.40 \geq t_{50} \geq 2.30$	$6.40 \geq t_{50} \geq 2.30$
t_{10} (ms)	$6.90 \geq t_{10} \geq 3.00$	$9.20 \geq t_{10} \geq 3.10$	$19.60 \geq t_{10} \geq 4.00$	$19.60 \geq t_{10} \geq 4.00$
NOTE α = $\sqrt{E/360}$, where E=selected energy that would be delivered to a 50-ohm resistive load I_p = peak current of the waveform $ I_R $ = absolute value of the reverse current of the waveform $ I_{20 \text{ max}} $ = maximum current after 20 ms for any patient impedance between 25 and 125 ohms t_r = 10% to 90% risetime of the first lobe of the current waveform t_{50} = waveform associated with the 50 percentage points of the first lobe of the current waveform t_{10} = waveform associated with the 10 percentage points of the first lobe of the current waveform				

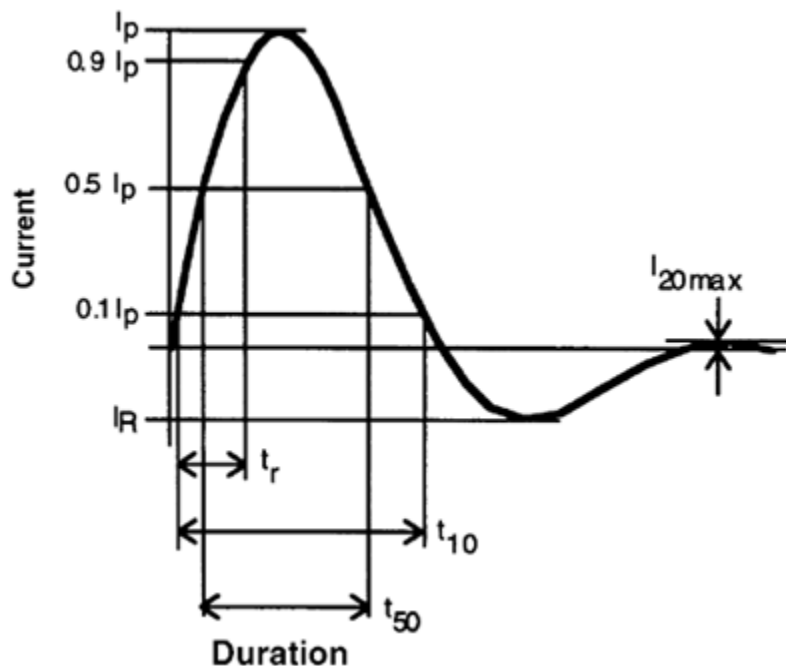


Figure 1—Damped sinusoidal waveform parameters

4.3.3 Energy accuracy

The delivered pulse energy shall be within 2 joules or $\pm 15\%$ of the selected energy indicated on the energy-level indicator of 3.3.10.2, whichever is greater, when discharged into a 50-ohm resistive load. The delivered pulse energy shall be within 3 joules or $\pm 40\%$ of the selected energy indicated on the energy-level indicator of 3.3.10.2, whichever is greater, when discharged into any resistive load between 25 and 100 ohms. At all energy settings, the actual delivered energies shall be related monotonically to the energy settings.

4.3.4 Discharge waveforms

The pulse shape (waveform) shall be either damped sinusoidal, monophasic truncated exponential, or other waveform as provided below and shall conform to the following requirements:

4.3.4.1 Damped sinusoidal waveform

Output waveforms that are obtained by discharging a capacitor through a waveshaping inductor shall meet the requirements of table 1 as shown in figure 1.

Table 2¾ Specifications for monophasic truncated exponential output waveforms

Load Resistance				
Waveform Parameter	25 Ohms	50 Ohms	100 Ohms	125 Ohms
I_p max (amperes)	80	40	20	20
tilt, max (percent)	80	80	80	80
t_d max (ms)	20	24	40	40
t_d min (ms)	3	3	3	3

NOTE

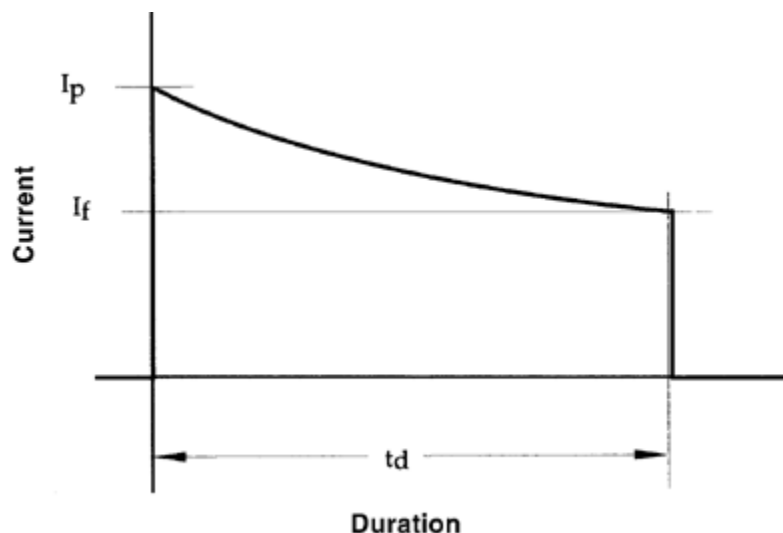
I_p = peak current of the waveform

I_f = final waveform current at time of truncation

tilt,max = $(I_p - I_f)/I_p \leq 80\%$ for all patient impedances between 25 and 125 ohms

t_d max = maximum waveform duration for any patient impedance between 25 and 125 ohms

t_d min = minimum waveform duration for any patient impedance between 25 and 125 ohms for energies greater than 5 joules

**Figure 2¾ Truncated exponential waveform parameters**

4.3.4.2 Monophasic truncated exponential waveform

Output waveforms that are obtained by truncating a capacitor discharge shall meet the requirements of table 2 as shown in figure 2.

4.3.4.3 Other waveforms

Other waveforms are not precluded from this standard if the following conditions are met:

- Efficacy is demonstrated in a prospective, randomized, masked (blinded) comparative clinical trial versus control waveforms that have met the requirements of this standard.
- Dosing procedures (e.g., electrode placement, energy delivery protocols) for the proposed waveforms are tested as part of the trial.
- Sufficient statistical power is employed in the study, design, and analysis. The 95% upper-confidence limit on the difference between the control and study waveform defibrillation rates should not exceed 10%.

- d) Results of the study are accepted for publication in manuscript form in a peer-reviewed journal.
- e) Performance specifications for commercial devices employing the proposed waveforms are published and available. Specifications shall be sufficient to allow independent verification that the parameters of the waveform output by the device replicate the conditions of the efficacy study.

4.3.5 Pulse rate

The defibrillator shall be able to deliver 15 pulses with energies of E_{MAX} into a 50-ohm resistive load in fewer than 5 minutes. In addition, the defibrillator shall not suffer permanent performance degradation as the result of 4 consecutive discharges of E_{MAX} into a 50-ohm resistive load at the maximum repetition rate. For battery-powered defibrillators operating at 0° C (32° F), the requirement for pulse rate may be relaxed to 10 pulses within 5 minutes.

4.3.6 Charge time

A completely discharged defibrillator shall be able to charge to E_{MAX} within 15 seconds, under conditions of 90% of rated mains input voltage or with batteries depleted by delivery of 15 discharges of E_{MAX} at 20° C (68° F). For battery-powered defibrillators, charge time to E_{MAX} shall be less than 20 seconds at 0° C (32° F).

4.3.7 Battery capacity and shelf life

The capacity of a fully charged battery shall be such that, at 0° C (32° F), the defibrillator can provide at least 20 discharges of E_{MAX} in cycles, each cycle comprising 3 discharges in 1 minute and 1 minute of rest.

After full charging of the battery, battery-powered defibrillators shall be stored for 7 days at 20° C (68° F) and 65% relative humidity. Afterwards, the defibrillator shall be capable of delivering 15 discharges of E_{MAX} at the rate of 1 per minute. The charge time for the final cycle shall be less than 15 seconds.

4.3.8 Energy loss rate

The defibrillator shall be able to deliver a pulse of 85% or more of the initial deliverable energy, at temperatures up to 45° C (113° F), for a period of at least 30 seconds after charge completion or for the duration of the period before automatic disarm is activated, whichever is longer. For defibrillators that use a refresh feature to maintain the desired energy charge, the discharge may be inhibited during the refresh period provided that 1) the charge indicator properly reflects the ready status of the device, 2) the instrument returns to the ready status upon completion of the refresh cycle (even if the discharge controls are inadvertently activated during the refresh period), and 3) the instruction manual fully describes any operating restrictions during the refresh cycle.

4.3.9 Automatic disarm

A charged defibrillator shall automatically disarm if not intentionally discharged within a certain period. Automatic disarm normally shall occur 30 to 120 seconds after charge completion. The length of this period shall be specified in the operating instructions discussed in 4.2. For special applications (for example, in the electrophysiology lab), it might be desirable to choose a longer period before activation of the automatic disarm. If a period of time longer than 120 seconds is used, the defibrillator shall be labeled with the following statement: "WARNING: This defibrillator remains armed for xxx second after reaching selected energy."

Activation of automatic disarm shall be accompanied by an audible signal to the operator. For instance, if a steady beeper tone is initiated when the defibrillator charge is completed, this "ready" tone may be terminated when automatic disarm is activated. In addition, it is recommended that activation of automatic disarm be visually indicated, for example, by a message displayed on the monitor screen or printed on the recorder.

4.3.10 Control 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, an inclusive outline, or an easily distinguishable contrasting patch, excluding those controls on the paddle electrodes. The controls and indicators within the defined outline shall be limited to the following or to controls that are combinations of the following:

- a) OFF/ON control and ON indicator;
- b) DISARM markings (optionally associated with the OFF condition of the OFF/ON control);
- c) energy select control;
- d) charge control;
- e) energy level indicator;
- f) charge indicator (necessary only if the stated requirements are not fulfilled by item [e]; otherwise optional).

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

4.3.10.1 Operating mode indicator

Any operating mode other than that required for ventricular defibrillation shall be clearly indicated.

4.3.10.2 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.

4.3.10.3 Charge indicator

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

4.3.10.4 Low-battery-charge indicator

A means shall be provided by which the defibrillator operator can determine when nonrechargeable batteries require replacement or when rechargeable batteries require charging. The defibrillator shall be capable of at least one and preferably three or more charge and discharge cycles at E_{MAX} after the low-battery-charge indicator has been activated.

4.3.10.5 OFF/ON

The defibrillator shall have a control that interrupts power to the functional circuits. The OFF/ON condition shall be clearly indicated.

4.3.10.6 Mode selection

The normal operating mode shall be that required for ventricular defibrillation. The defibrillator shall be in the normal mode upon application of power. Manual action shall be required to change to any mode other than the normal mode, and the selected mode shall be clearly indicated.

4.3.10.7 Charge control

The defibrillator shall have a control that initiates charging of the internal energy storage device. The charging sequence shall require manual initiation after each discharge into the patient circuit.