List of Titles

American National Standard

ANSI/AAMI DF2:1996

Cardiac defibrillator devices

AAMI Association for the Advancement of Medical Instrumentation

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

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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
John Anderson, Faculty of Ulster Polytechnical
Robert Bain, CBET, Johns Hopkins University Hospital
Alan S. Berson, PhD, National Heart, Lung and Blood Institute
Francis Charbonnier, PhD, Hewlett-Packard Company
Richard A. Crampton, MD, University of Virginia, American College of Cardiology
Stephen L. Daleo, Nellcor
Regis De Silva, MD, Harvard Medical School
Joseph A. Gascho, MD, The M. S. Hershey Medical Center
Leslie A. Geddes, PhD, Purdue University

Mike Guzzetta, Mennen Medical, Inc.
John R. Helland, Incontrol, Inc.
Glenn Isensee, Burdick, Inc.
Janice Lorraine Jones, PhD, Georgetown University
John L. Karpowicz, Laerdal Manufacturing Corporation
Richard Kerber, MD, University of Iowa, University Hospital
Martin J. Kutik, PPD Consulting
David Linhares, SpaceLabs Medical, Inc.
Dilip N. Mehta, Medical Research Laboratories
Michael Molyneux, Kilovac Corporation
Carlton B. Morgan, Heartstream, Inc.
Kenneth F. Olson, SurVivaLink Corporation
Vincent J. B. Pierdominici, Jr., FDA/Winchester Engineering and Analytical Center
Harry S. Robbins, Defense Personnel Support Center
David Schlageter, Marquette Electronics, Inc.
Joseph Seemann, Cardiac Science, Inc.
W. A. Tacker, Jr., MD, PhD, Purdue University
Kok-Swang Tan, PhD, Bureau of Radiological Medical Devices, Canada
W. Douglas Weaver, MD, University of Washington Hospital
Robert C. Wesley, Long Beach, VA Medical Center
Michael D. Willingham, Physio Control Corporation

Alternates: Robert J. Cangelosi, FDA/Center for Devices and Radiological Health
Carole Carey, FDA/Center for Devices and Radiological Health
Marc Denitz, Kilovac Corporation
D. Craig Edwards, First Medic (SpaceLabs)
John Kuphal, Laerdal Manufacturing Corporation
Martin Rockwell, Hewlett-Packard Company
William Smirles, Medical Research Laboratories

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, μA, nA	Ampere, milliampere, microampere, 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 defibrilltor/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 (milliampere (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)	$96\alpha \geq I_p \geq 55\alpha$	$66\alpha \geq I_p \geq 45\alpha$	$46\alpha \geq I_p \geq 25.1\alpha$	$46\alpha \geq I_p \geq 20\alpha$
$\lvert I_R \rvert$(amperes)	$\lvert I_R \rvert \leq 0.40\ I_p$	$\lvert I_R \rvert \leq 0.40\ I_p$	$\lvert I_R \rvert \leq 0.40\ I_p$	$\lvert I_R \rvert \leq 0.40\ I_p$
$\lvert I_{20\ max} \rvert$(amperes)	$\lvert I_{20\ max} \rvert \leq 0.01 I_p$	$\lvert I_{20\ max} \rvert \leq 0.015 I_p$	$\lvert I_{20\ max} \rvert \leq 0.04 I_p$	$\lvert I_{20\ max} \rvert \leq 0.075 I_p$
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

$\lvert I_R \rvert$ = absolute value of the reverse current of the waveform

$\lvert I_{20\ max} \rvert$ = 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

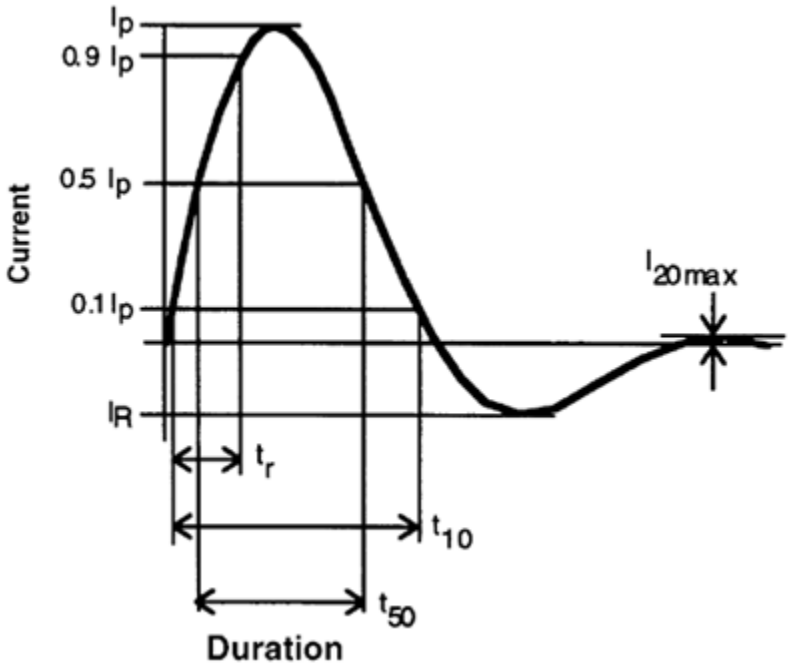

Figure 1—Damped sinusoidal waveform parameters

4.3.3 Energy accuracy

The delivered pulse energy shall be within 2 joules or ±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 ±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

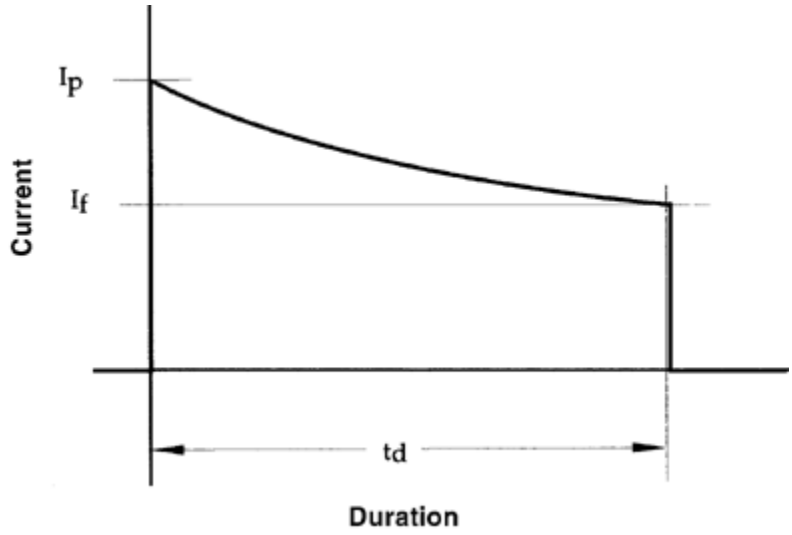

Figure 2¾ Truncated exponential waveform parameters

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:

a) Efficacy is demonstrated in a prospective, randomized, masked (blinded) comparative clinical trial versus control waveforms that have met the requirements of this standard.

b) Dosing procedures (e.g., electrode placement, energy delivery protocols) for the proposed waveforms are tested as part of the trial.

c) 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.

4.3.10.8 Discharge control

The defibrillator or its paddle electrodes shall have a control or controls that initiate discharge of the selected energy into the patient circuit.

4.3.11 Open/shorted discharge

If construction of the defibrillator paddle electrodes allows them to contact each other, then the defibrillator shall not suffer significant performance degradation when the electrodes are shorted together. Significant performance degradation is defined as failure to comply with all requirements of the standard, by 10 energy discharges of E_{MAX}, at intervals of no more than 3 minutes each, when the electrodes are shorted together. Also, the defibrillator shall not show significant degradation of performance by 10 energy discharges at E_{MAX} with the paddle electrodes open-circuited and one paddle electrode grounded, as specified in the test section.

NOTE—This procedure should not be performed in user testing. Repeated discharges of E_{MAX} with the paddle electrodes shorted or open will shorten life, and cause eventual failure of the equipment, and could be hazardous to the operator.

4.3.12 Disarm

Five or more seconds after removal of power to the functional circuits, either by unplugging of the line cord, by operation of the OFF/ON control, or by operation of the DISARM control, and independent of operator intervention, the defibrillator shall not present a voltage at the output. Defibrillators with a battery backup mode for the functional circuitry shall not be required to disarm by unplugging of the line cord.

4.3.13 Reduce-charge capability

The defibrillator shall have a means by which the operator can internally discharge the defibrillator to reduce the energy selected from the maximum energy level to the minimum energy level in 20 seconds or less, without the ECG monitor, if present, being turned off.

4.3.14 Paddle electrodes

4.3.14.1 Insulation

At a peak voltage equal to 1.5 times the magnitude of the maximum voltage occurring in the energy storage capacitor at the maximum energy setting, the 60-Hz leakage current flowing between the paddle grip of one paddle and the electrode of that paddle and, in turn, the other paddle electrode shall not exceed the 250-microampere peak. If measurement at 50 Hz is preferred, the 50-Hz leakage current shall not exceed the 210-microampere peak.

4.3.14.2 Active patient contact area

The minimum contact area per electrode shall be

a) 50 cm^2 each electrode, 150 cm^2 total for adult transthoracic use;

b) 32 cm^2 for adult internal use;

c) 15 cm^2 for pediatric transthoracic use;

d) 9 cm^2 for pediatric internal use.

For purposes of this section, an “adult” is defined as a patient weighing over 10 kg, and “pediatric” as a patient weighing 10 kg or less.

4.3.15 Self-adhesive electrodes for monitoring and defibrillation, and (optionally) pacing

4.3.15.1 AC small signal impedance

The 10-Hz impedance for any of at least 12 electrode pairs connected gel-to-gel, at a level of impressed current not exceeding 100 microamperes (μA) peak-to-peak, shall not exceed 3 kilohms. The impedance at 30 kHz shall be less than 5 ohms.

4.3.15.2 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 3 ohms.

4.3.15.3 Combined offset instability and internal noise

A pair of electrodes connected gel-to-gel shall generate, after a 1-minute stabilization period, a voltage no greater than 100 μV peak-to-peak in the pass band of 0.5 to 40 Hz, for a period of 5 minutes following the stabilization period.

4.3.15.4 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 400 mV at 4 seconds and 300 mV at 60 seconds after the last shock delivery.

4.3.15.5 Biological response

The electrode shall be biocompatible. For this application, with the electrode in continuous contact with the skin for the maximum duration specified by the manufacturer, biocompatibility requires evaluation of cytotoxicity, skin irritation, and skin sensitization.

4.3.15.6 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 100 mV.

4.3.15.7 Bias current tolerance

The observed DC voltage offset change across a pair of electrodes connected gel-to-gel shall not exceed 100 mV 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).

4.3.15.8 Electrode active area

The minimum active (gel) area of self-adhesive electrodes used for defibrillation and pacing shall be

each	together	purpose
50 cm^2	150 cm^2	adult transthoracic
15 cm^2	45 cm^2	pediatric (less than 10 kg) trans-chest

4.3.15.9 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. Data on the characteristics of the adhesive (peel strength, setting time, response to perspiration, effect of temperature on these characteristics) should be available from the vendor.

4.3.15.10 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 for 1 year at 35° C (95° F). One-year storage may be simulated by accelerated testing at higher temperatures. Electrodes shall comply after storage for 24 hours at –30° C (–86° F) and +65° C (149° F). Electrodes shall be returned to a temperature in the range of 15° C to 35°C before the test for compliance is performed.

4.3.15.11 Universal-function electrodes

If the electrodes are designed and intended for use in all three modes, i.e., monitoring, defibrillation, and 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 electrode shall meet all requirements of 4.3.15 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.

4.3.15.12 Cable length

The electrode cables shall have an extended length of at least 2 meters. If coiled cords are used, the extension force shall be 18 newtons (4 lb) or less per paddle electrode at a distance of 2 meters.

4.3.16 Electrical risk currents

Chassis leakage, defibrillation electrode source, and sink currents shall be in accordance with 2.4, the American National Standard *Safe Current Limits for Electromedical Apparatus*, (with isolated patient connection), except that the allowable sink and source leakage current per paddle electrode shall become 100 microamperes for external paddle electrodes and 50 microamperes for internal paddle electrodes. These patient leakage currents shall be measured with the output switching device in both the quiescent and the activated condition.

4.3.17 Synchronized discharge

Synchronized discharge is not a required feature of a defibrillator. A defibrillator and a monitor are needed to perform synchronized cardioversion. It is strongly recommended that the defibrillator and the monitor be integrated into a single instrument to ensure proper interfacing.

The operator shall be made aware, in the manual as a minimum, that ECG acquisition should be accomplished through monitor leads or self-adhesive defibrillator electrodes rather than through defibrillator paddle electrodes. A marker shall appear on the monitor screen to mark the times when the monitor has recognized R waves and is producing a signal to trigger defibrillator discharge. The peak of the defibrillator discharge shall occur within 60 milliseconds of the peak of the R wave if the defibrillator and monitor are combined in a single instrument. If an independent monitor is used, which is not recommended, the defibrillator shall effect the discharge within 25 ms of the application of the most recent synchronizing signal provided by the monitor. This presumes that the monitor correctly detects R waves and provides its synchronizing signal within 35 ms of the R-wave peak so that the overall delay from R wave to discharge does not exceed 60 ms, as is needed for safe synchronized cardioversion. Therefore, the operator who elects to use an independent monitor should be familiar with that monitor and should be satisfied that the defibrillator monitor combination works properly and safely. If the defibrillator can accept an externally applied synchronizing signal, the required signal characteristics shall be specified in the operating manual.

4.3.18 Electromagnetic compatibility (EMC) requirements

These EMC requirements were developed on the basis of reference standards 2.5, 2.6, and 2.8.

4.3.18.1 Electromagnetic emissions

4.3.18.1.1 Radiated and conducted EM emissions

The defibrillator shall comply with the requirements of 2.8 (CISPR 11), group 1, in all configurations and operating modes. Defibrillators are classified as Class B equipment for determining applicable CISPR 11 requirements.

Emission levels measured 10 meters from the instrument shall not exceed 30 dB μV from 30 MHz 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.

4.3.18.1.2 Magnetic field emissions

The unit shall not emit a magnetic field intensity greater than 400 A/m (magnetic flux density 5 gauss) at any point on the surface of the instrument under normal operating conditions. This requirement is waived within 5 cm of speakers or other devices that intentionally generate intense localized magnetic fields. This requirement does not apply during the charge/discharge cycle.

4.3.18.2 Electromagnetic immunity

4.3.18.2.1 Immunity to radiated rf EM fields

The test methods and instruments specified in 2.5, International Electrotechnical Commission (IEC) 1000-4-3, 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: 80 MHz to 1 GHz;

c) AM modulation, 80 % index, at one frequency near the geometric mean of the ECG passband.

The defibrillator's combination defibrillation/monitoring electrodes are terminated in a simulated patient load (1 kΩ 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 (3 V/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.

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

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

4.3.18.2.2 Immunity to conducted EM fields

The test methods and instruments specified in the current draft of 2.5, IEC 1000-4-6 apply.

When a defibrillator can be operated from line power as well as a 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 80 MHz;

c) AM modulation, 80 % index, at one frequency near the geometric mean of the ECG passband.

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.

4.3.18.2.3 Immunity to magnetic fields

The test methods and instruments specified in the current draft of 2.5, IEC 1000-4-8 apply.

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

a) magnetic field intensity: 80 A/m (magnetic flux density 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, and stored data should not be lost or corrupted.

4.3.18.2.4 Immunity to electrostatic discharge (ESD)

The test methods and instruments specified in 2.5, IEC 1000-4-2 apply.

The instrument is exposed, at any point on its surface accessible to the operator or patient, to open air discharges up to 8 kV or direct contact discharges up to 6 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. There shall be no unintended energy delivery, unsafe failure mode, or loss of stored data.

4.3.18.2.5 Power line transients

a) *Fast transient/bursts*. The test methods and instruments specified in 2.5, IEC 1000-4-4 apply. Mains connectable instruments shall meet a 1-kV immunity level at the mains plug. Only transient loss of functionality is allowed. No inadvertent energy delivery or other unintentional change of state 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 specified in 2.5, IEC 1000-4-5 apply. Mains connectable equipment shall meet an immunity level of 1 kV line-to-line and 2 kV line-to-ground. No inadvertent energy delivery or other unintentional change of state is allowed. The device should revert to its prior condition without operator intervention.

4.3.19 External pacing

External pacing may be provided as an optional feature.

4.3.19.1 Pacing mode activation

The pacing mode shall only be activated manually by the mode selector and shall be clearly labeled. The defibrillator shall be disarmed and the defibrillation mode disabled when the pacing mode is operative.

4.3.19.2 Pacing delivery

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

4.3.19.2.1 Separate pacing pathway

If a separate pacing electrode pathway is provided, the following requirements 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 minutes apart across the pacing electrode pads shunted by a 100-ohm load.

4.3.19.2.2 Combined pathway

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

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

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

c) The electrodes shall meet all the requirements of 4.3.15.

4.3.19.3 Pacing pulse shape and duration

4.3.19.3.1 Pace pulse duration accuracy

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

4.3.19.3.2 Pace pulse duration stability

a) If the pacemaker is battery-operated, the pulse duration shall not change by more than ±10% over the duration equivalent to the nominal operating time of the battery as specified in the operating instructions.

b) If the pacemaker is powered off AC-mains, the pulse duration shall not change by more than ±10% over the duration of the maximum length of treatment with a given set of electrodes as specified in the operating instructions.

4.3.19.4 Pacing pulse current

4.3.19.4.1 Pacing pulse current accuracy

If predetermined within the pacer, the pacing pulse current shall be described in the operating instructions.

The output waveform shall be within the limits specified in the operating instructions.

4.3.19.4.2 Pacing pulse current stability

a) If the pacemaker is battery-operated, the pulse current shall not change by more than ±10% over the duration equivalent to the nominal operating time of the battery specified in the operating instructions.

b) If the pacemaker is powered off AC-mains, the pulse current shall not change by more than ±10% over the duration of the maximum length of treatment with a given set of electrodes as specified in the operating instructions.

4.3.19.5 Pacing rate

4.3.19.5.1 Pacing rate accuracy

The output waveform shall be within the limits specified in the operating instructions.

4.3.19.5.2 Pacing rate stability

a) If the pacemaker is battery-operated, the pulse rate shall not change by more than ±10% over the duration equivalent to the nominal operating time of the battery as specified in the operating instructions.

b) If the pacemaker is powered off AC-mains, the pulse rate shall not change by more than ±10% over the

duration of the maximum length of treatment with a given set of electrodes as specified in the operating instructions.

4.3.19.6 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 shall be labeled with the available selections.

4.3.19.7 Demand pacing

Demand pacing is not a required feature of defibrillators including external pacing capability. If demand pacing is available, the heart rate at which pacing begins, in a down-trending heart rate, shall be between 90% and 100% of the pacing rate selected on the unit. If the unit has rate settings below 40 ppm, the unit shall begin pacing when the heart rate drops below the rate setting minus 4 ppm.

4.3.19.8 Pacer lead-off indication

There shall be a clear indication by means of either a display or an indicator light that the unit is unable to deliver the pacing current because of a pacing leads-off condition. It is recommended, though not required, that the unit also provide an audible indicator of this condition.

4.4 Requirements for physical characteristics

4.4.1 Cable length

The paddle electrode cables, for those units where paddle electrodes are not integral, shall have a minimum extended length of 2 m (80 in) when measured from the connector or cable exit of the defibrillator to the entry of the cable into the paddle housing with an extension force of 18 newtons (4 lbs) or less per paddle electrode in the case of coiled cords.

4.4.2 Paddle electrode mechanical shock resistance

Cable-connected defibrillator paddle electrodes shall not suffer degradation of performance by either breakage or distortion when subjected to five successive drops, in each of the six directions defined by three mutually perpendicular axes (30 drops total), from a height of 1 m (40 in) to an asphalt-tiled concrete floor.

4.4.3 Cleaning or sterilization

The operator manual shall include instructions for cleaning external paddle electrodes and for sterilizing internal paddle electrodes. The paddle electrodes shall be capable of withstanding at least 50 cleaning or sterilization cycles in accordance with the manufacturer's instructions while complying with all the requirements of this standard.

4.4.4 Device markings

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. The capital letters of the words in the notices required by 4.1.1 shall have a minimum height of 2.8 mm (7/64 in).

5 Tests

This section defines the referee test methods by which compliance of the equipment with the requirements of section 4 can be verified; the paragraph numbers below correspond with the paragraph numbers of section 4. These test methods are not intended for use by end users of the device. Also, every defibrillator manufactured need not be tested completely, as the methods are intended for type testing.

5.1 Device labeling

Compliance with the device labeling requirements of 4.1 can be verified by inspection.

5.2 Operating instructions and maintenance manuals

Compliance with the requirements of 4.2 can be verified by inspection.

5.3 Essential requirements

a) *Test apparatus*. The following types of apparatus are required for performing the tests of 4.3: 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, 100-ohm, and 125-ohm resistive test loads with sufficient energy absorptive capability (E_{MAX}); ac high-potential tester; wire; the test apparatus needed for evaluating risk currents described in 2.4; temperature and humidity chambers capable of 0° C to 45° C + 1.4° C and 30% to 95% + 5% RH; hyper-/hypobaric chambers capable of 700 hPa to 1060 hPa; vibration and shock tables as specified in 2.9; and water spray apparatus as specified in 2.7.

b) *Accuracy*. The accuracy of instruments and test equipment used to control or monitor the test parameters shall be verified as recommended by the manufacturer, documented, and a calibration sticker shall be affixed to the instrument. All instruments and test equipment used in conducting the tests specified herein shall

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

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

3) be appropriate for measuring the test parameters.

c) *Low-temperature tests*. For all tests of defibrillators at 0° C, the defibrillator shall be placed in a temperature chamber at 0° C for 2 hours prior to the test to allow equilibration of the defibrillator components to the environmental temperature.

5.3.1 Operating conditions

a) *Vibration tests*. The test methods and instruments specified in 2.9, Method 514.4, apply. The specific test category and test duration are selected based on the designed and labeled use of the defibrillator, as specified in 3.3.1 of this document. For defibrillators designed and labeled for air/helicopter transport, the manufacturer may choose the test category from among those listed in 3.3.1 and shall disclose in the user documentation the specifics of the test performed.

b) *Shock/drop tests*. The test methods and instruments specified in 2.9, Method 516.4, apply. Procedure I (Functional shock) shall be followed at the level and repetitions specified in 3.3.1 of this document.

c) *Enclosure protection, solid foreign object ingress and water ingress*. The test methods and instruments specified in 2.7 apply. The specific test levels are selected based on the designed and labeled use of the defibrillator, as specified in3.3.1 of this document.

5.3.2 Energy range

a) Select the minimum nonzero discharge energy and initiate the charge.

b) Immediately upon completion of the charge, apply the paddle electrodes to the defibrillator tester and discharge the defibrillator.

c) For defibrillators not capable of synchronized discharge, the delivered energy as indicated on the tester

shall be greater than 0 joules but less than 14 joules. For defibrillators capable of synchronized discharge, the delivered energy indicated on the tester shall be greater than 0 joules but less than 9 joules.

d) Inspect the energy select control and verify that E_{MAX} is between 250 joules and 360 joules inclusive.

e) Select E_{MAX} and initiate the charge.

f) Immediately upon completion of the charge, apply the paddle electrodes to the defibrillator tester and discharge the defibrillator.

g) The delivered energy indicated on the tester shall be within 15% of E_{MAX} as indicated on the energy level indicator.

5.3.3 Energy accuracy

a) Select E_{MAX} and initiate the charge.

b) Immediately upon completion of the charge, apply the paddle electrodes to the defibrillator tester and discharge the defibrillator.

c) The delivered energy indicated on the tester shall be within 2 joules or ±15%, whichever is greater, of the indicated energy.

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

e) Repeat steps a) and b). The delivered energy indicated on the tester shall be within 1.5 joules or ±40%, whichever is greater, of one-half of the indicated energy.

f) 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.

g) Repeat steps a) and b). The delivered energy indicated on the tester shall be within 1.5 joules or ±40%, whichever is greater, of one-half of the indicated energy.

h) For defibrillators not capable of synchronized discharge, repeat steps a) through g) for a selected energy of 10 joules, and for an intermediate energy level between E_{MAX} and 10 joules.

i) Verify the monotonic relationship between all measurements taken in 5.3.2.

For defibrillators capable of synchronized discharge, repeat steps a) through g) for a selected energy of 5 joules and for an intermediate energy level between E_{MAX} and 5 joules.

NOTE—The aforementioned test is based on a defibrillator tester calibrated for a 50-ohm resistive load. Therefore, in steps e) and g) factors of one-half appear.

5.3.4 Discharge waveforms

5.3.4.1 Damped sinusoidal waveform

a) Connect the 25-ohm resistive test load and an oscilloscope between paddle electrodes.

b) Select E_{MAX} and discharge the defibrillator.

c) Analyze the current waveform and determine $|I_p|$, $|I_{20max}|$, $t_{R'}$, $t_{50'}$, and t_{10}. These parameters shall fall within the limits established in table 1 of section 3.

d) Repeat steps a) through c) for a 50-ohm, 100-ohm, and 125-ohm resistive load.

5.3.4.2 Monophasic truncated exponential waveform

a) Connect the 25-ohm resistive test load and an oscilloscope between paddle electrodes.

b) Select E_{MAX} and discharge the defibrillator.

c) Analyze the current waveform and determine I_p, tilt, $t_{d\ max}$', and $t_{d\ min}$. These parameters shall fall within the limits established in table 2 of section 3.

d) Repeat steps a) through c) for a 50-ohm, 100-ohm, and 125-ohm resistive load.

5.3.4.3 Other waveforms

Perform tests as prescribed by the manufacturer per the provisions of section 4.

5.3.5 Pulse rate

a) For battery-powered units, fully charge the battery according to the manufacturer's instructions. For linepowered units, measure the power line voltage to make sure that it remains within the range specified by the manufacturer during charging of the defibrillator.

b) Apply the paddle electrodes to the defibrillator tester and select an energy level of E_{MAX}.

c) Simultaneously initiate the charge and a timer.

d) Immediately upon completion of the charge, discharge the defibrillator. Repeatedly charge and discharge the defibrillator approximately every 20 seconds into a 50-ohm resistive test load for a total of 15 repetitions. The first and fifteenth tests should be into a defibrillator tester. The first and fifteenth pulses shall be within 4 joules or ±15% whichever is greater, of the indicated energy.

e) Completion of the fifteenth discharge shall occur no later than 5 minutes after the initiation of the first charge. When testing battery-powered defibrillators at 0° C (32° F), only 10 charge-discharge cycles shall be required within a 5-minute period.

f) Wait 10 minutes, then connect the 50-ohm resistive test load to the paddle electrodes and select an energy level of E_{MAX}.

g) Charge and discharge the defibrillator four consecutive times as quickly as possible. Each discharge following the first shall be effected when either of the following is observed: the charge indicator operates, or the energy level indicator reaches 90% of the selected energy. Each discharge shall be effected as soon (after the observation) as the defibrillator is capable of being discharged.

h) The defibrillator shall be capable of passing all of the other performance tests of this standard at the completion of steps f) and g).

5.3.6 Charge time

This test is performed in conjunction with test 5.3.5 on pulse rate.

a) After completion of the fifteenth discharge at 20° C (68° F) (steps d) and e) of test 5.3.5), simultaneously initiate charging and start the timer. Stop the timer when the charge indicator reaches the ready condition. Verify that charge time is less than 15 seconds.

b) Power the defibrillator at 90% of rated mains voltage. Simultaneously initiate charging and start the timer. Stop the timer when the charge indicator reaches the ready condition. Verify that charge time is less than 15 seconds.

c) With battery-powered defibrillators, after completing the tenth discharge at 0° C (32° F) (steps d) and e)

of test 5.3.5), simultaneously initiate charging and start the timer. Stop the timer when the charge indicator reaches the ready condition. Verify that charge time is less than 20 seconds.

5.3.7 Battery capacity and shelf life

5.3.7.1. Battery capacity test

a) Fully charge the battery according to the manufacturer's instructions. Establish an environmental temperature of 0° C (32° F) and let the defibrillator equilibrate for at least 2 hours.

b) Apply the paddle electrodes to the defibrillator tester and select an energy level of E_{MAX}.

c) Simultaneously initiate the charge and a timer.

d) Perform 20 discharges in cycles, each comprising 3 discharges in 1 minute and 1 minute of rest.

e) Verify that E_{MAX} is achieved on the twentieth charge-discharge episode.

5.3.7.2 Battery shelf life test

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

b) Apply the paddle electrodes to a 50-ohm defibrillator tester and select an energy of E_{MAX}.

c) Simultaneously initiate the charge and the timer.

d) Immediately upon completion of the charge, discharge the defibrillator. Repeatedly charge and discharge the defibrillator approximately every 60 seconds for a total of 15 repetitions.

e) Completion of the fifteenth discharge shall occur no later than 15 minutes after initiation of the timer. In addition, the charge time for the 15th charge shall not exceed 15 seconds.

5.3.8 Energy loss rate

a) Select E_{MAX}, initiate the charge, and apply the paddle electrodes to the defibrillator tester.

b) Immediately upon completion of the charge, discharge the defibrillator. Note the indicated delivered energy.

c) Charge the defibrillator to E_{MAX} and apply the paddle electrodes to the defibrillator tester.

d) Discharge the defibrillator exactly 30 seconds after completion of the charge or just before automatic disarm would be activated, if longer. Note the indicated delivered energy.

e) The energy level noted in step d) shall be no less than 85% of that noted in step b).

f) Inspect the operating instructions to verify disclosure of the time between completion of charge and decay to 85% of charge.

5.3.9 Automatic disarm

a) Select E_{MAX} and initiate the charge.

b) Initiate the timer at the instant when chargedone is complete. Verify that the charge done tone has started.

c) Note the time when automatic disarm is activated. Verify that this time is between 30 and 120 seconds. Also verify that the chargedone tone stopped upon activation of automatic disarm.

5.3.10 Control indicators to 5.3.10.3 Charge indicator

Compliance with these requirements can be verified by inspection.

5.3.10.4 Low-battery-charge indicator

a) Perform this test concurrently with the battery shelf life test.

b) Continue to charge and discharge the defibrillator at E_{MAX} approximately every 60 seconds into a 50-ohm load until the low-battery-charge indicator activates. Discharge the defibrillator.

c) Verify that the defibrillator is capable of at least one more charge and discharge at E_{MAX}.

5.3.10.5 OFF/ON to **5.3.10.8 Discharge control**

Compliance with these requirements can be verified by inspection.

5.3.11 Open/shorted discharge

a) Select E_{MAX}, initiate the charge, and bring the paddle electrodes together.

b) Upon completion of the charge, discharge the defibrillator.

c) Repeat this charge-discharge cycle 9 times at 3-minute intervals.

d) Select E_{MAX} and, with the paddle electrodes open circuited and one electrode connected to earth ground, initiate the charge.

e) Upon completion of the charge, discharge the defibrillator.

f) Repeat steps d) and e) four times.

g) Repeat steps d), e), and f) with the other electrode connected to earth ground.

h) The defibrillator shall be able to pass all the other performance tests of this standard after completion of these tests.

NOTE—This procedure should not be performed during user testing. Repeated discharges of E_{MAX} with the paddle electrodes shorted or open will shorten life and cause eventual failure.

5.3.12 Disarm

a) Connect a storage oscilloscope or strip chart recorder to the output of a defibrillator tester.

b) Charge the defibrillator to E_{MAX}.

c) Simultaneously turn off the power and start a timer.

d) At an elapsed time of 5 seconds, discharge the defibrillator, if possible, and observe the trace recorded on the oscilloscope or the strip chart recorder.

e) The peak voltage shall not exceed 0 ±1V.

f) Repeat steps b) through e) with the oscilloscope or strip chart recorder connected between paddle electrode and ground.

5.3.13 Reduce-charge capability

a) Study the operation of the defibrillator to determine how the requirements of 4.3.13 are implemented (for example, using a reduce-charge control, switching the defibrillator off, and activating the disarm control).

b) Select E_{MAX} and initiate the charge.

c) After charge completion, select the minimum energy level (E_{MIN}), initiate the reduce charge, and simultaneously start a timer.

d) Stop the timer when the defibrillator is fully charged to E_{MIN}. The elapsed time shall be less than 20 seconds.

e) Deliver the stored energy to a 50-ohm defibrillator tester and verify that the delivered energy is within the accuracy limits specified in 4.3.3.

5.3.14 Paddle electrodes

5.3.14.1 Insulation

CAUTION—Use extreme care during the following test because of the high voltage involved.

a) Apply aluminum foil to the entire gripping surface of one paddle electrode with sufficient pressure to make it conform to the surface.

NOTE—For verification purposes, the gripping surface is defined as the approximately cylindrical area around each handle where the operator's fingers grasp the paddle electrode, but not beyond any barrier or curvature that is obviously intended to limit hand placement. The gripping surface also includes areas 1 inch in diameter centered on any control located on the paddle electrode, representing the location(s) of the operator's thumb or fingers or both.

b) With the paddle electrodes connected to the defibrillator, connect the high-potential lead of a 60-Hz (or 50-Hz, if preferred) high-potential test source to the aluminum foil. Connect the low-potential or ground lead to the paddle electrode. Slowly adjust the peak voltage amplitude of the test source to equal 1.5 times the maximum voltage occurring on the defibrillator energy storage capacitor. For a sine wave, this corresponds to an rms value of 1.06 times the capacitor voltage. Maintain this voltage for 1 minute. Repeat this test with the low-potential lead connected to the other paddle electrode.

c) There shall be no voltage breakdown, and the 60-Hz leakage current shall not exceed 250-microampere peak (177 microamperes rms); if a 50-Hz test source is used, the current shall not exceed 210-microampere peak (148 microamperes rms).

NOTE—When the output voltage is set as described in b), any leakage current that flows when the high-potential lead is disconnected from the foil represents internal leakage of the test apparatus and may be subtracted from the total current reading. Alternatively, an external ammeter may be placed in the ground circuit to eliminate this internal leakage and to enhance resolution, if necessary.

d) Repeat a) through c) using the other paddle electrode grip.

5.3.14.2 Active patient contact area

Compliance with 4.3.14.2 can be verified by measuring the dimensions and area of the electrode active contact surface. If the outside edges of the electrode are rounded with a radius of 0.125 inches or less, the area may be calculated based on outside dimensions while neglecting the effects of this curvature.

5.3.15 Self-adhesive electrodes for monitoring, defibrillation, and (optionally) pacing

5.3.15.1 AC small signal impedance

The impedance of a pair of electrodes connected gel-to-gel can be determined by applying a sinusoidal current of known amplitude and observing 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 μA p-p.

5.3.15.2 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 3:50.

5.3.15.3 Combined offset instability and internal noise

After a 1-minute stabilization period, the output voltage of the test circuit (derived from 2.3, ANSI/AAMI-EC12, figure 1) shall not exceed 100 µA p-p over 5 minutes. Output voltage shall be measured with an instrument having a frequency response of 0.01 to 1000 Hz and a minimum input impedance of 10 megohms.

5.3.15.4 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 400 mV at 4 seconds and 300 mV at 60 seconds.

5.3.15.5 Biological response

This section identifies the recommended tests and their purposes. The procedure for performing these tests are not given in this standard due to the variety of acceptable methods that may be employed. It is recommended that procedures and techniques currently being developed in the ISO 10993 series be considered when addressing these requirements (see, for example, 2.2).

5.3.15.5.1 Cytotoxicity

With the use of cell-culture techniques, these tests determine lysis of cells, the inhibition of cell growth, and other effects on cells caused by test material(s) and/or extracts from the materials.

5.3.15.5.2 Sensitization

These tests estimate the potential for contact sensitization of test materials, devices, and/or their extract(s) using an appropriate model. These tests are appropriate, because exposure to even minute amounts of potential leachables can result in allergic or sensitization reactions.

5.3.15.5.3 Irritation

These tests estimate the irritation potential of test devices, material(s), and/or their extract(s) using appropriate site or implant tissue such as skin, eye, and mucous membrane in a suitable mode. The test(s) performed should be appropriate for the route (skin, eye, mucosa) and duration of exposure to determine irritant effects of device materials and potential leachables.

5.3.15.6 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.

5.3.15.7 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 pair of 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 shall be measured at least once per hour over the period of observation. The initial offset voltage shall 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.

5.3.15.8 Electrode active area

Compliance with 4.3.15.8 can be verified by measuring the dimensions and area of the electrode active contact surface.

5.3.15.9 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 A4.3.15.9).

5.3.15.10 Packaging and shelf life

Compliance with 4.3.15.10 can be verified by conducting the tests of 5.3.15.1 through 5.3.15.9 at the end of the specified shelf life and at the extremes of the temperature ranges specified in 4.3.15.10.

5.3.15.11 Universal-function electrodes

a) Compliance can be verified by comparing the packaging description of the electrode's functions to the operating instructions.

b) Compliance with the labeling requirements 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 shall be subjected to the performance tests of 5.3.15.

5.3.15.12 Cable length

Compliance can be verified by measurement.

5.3.16 Electrical risk currents

The defibrillator shall be tested in accordance with 2.4, the American National Standard, *Safe Current Limits for Electromedical Apparatus* (isolated patient connection), using the limits specified in 4.3.16. The operation of the device under test must be investigated to determine if the output switching device can be activated long enough to perform the referenced leakage tests. If the output switching device cannot be activated long enough to perform the test, the activation may be simulated by bridging and opening the appropriate parts of the output circuit.

NOTE—This procedure of simulating the operation of the output switching device is not recommended for routine testing because of its complexity and because of the possibility of damaging the device.

5.3.17 Synchronized discharge

If the defibrillator has synchronizing capability, study the operating manual and set up the necessary equipment and interconnections to operate the unit in the synchronized mode. If the monitor has an adjustable ECG gain control, set it to the x1 (unity gain) position.

a) If an integrated monitor-defibrillator is used, apply the defibrillator electrodes to a 50-ohm test load. Apply a 1-mV peak, 70-ms wide pulse to the input of the monitor.

b) If an independent monitor is used, conduct the following test:

1) Apply the paddle electrodes to a 50-ohm resistive test load.

2) Connect a generator, having a repetition rate of 60 to 150 pulses per minute, to the synchronizer. All other characteristics of the signal shall be in accordance with the specifications that are required to be included in the operating instructions.

3) Connect one input of a dual-channel storage oscilloscope to the synchronizing circuit in order to measure the synchronizing signal. Couple the other input to one defibrillator paddle electrode or paddle electrode cable in a manner that introduces no more than a 1-ms phase delay.

4) Select the synchronized mode of defibrillator operation and charge the defibrillator.

5) Discharge the defibrillator and observe the traces on the oscilloscope.

6) The peak of the discharge shall have occurred within 25 ms of the synchronizing signal.

5.3.18 Electromagnetic compatibility (EMC) requirements

EMC measurements are complex for defibrillators because they are patient-coupled devices, which markedly affects 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 electrode cables shall be tested both in an unterminated mode and in a patient-simulated terminated mode.

NOTE—The requirements on EMC emissions are waived during the defibrillator charge/discharge cycle for reasons stated in the rationale.

5.3.18.1 Electromagnetic emissions

5.3.18.1.1 Radiated and conducted EM emissions

The instrument shall comply with 2.8 (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.

5.3.18.1.2 Magnetic field emissions

Use a gauss meter probe to verify that the instrument does not emit a magnetic field intensity greater than 400 A/m (5 gauss) at any point on the surface of the instrument under normal operating conditions.

5.3.18.2 Electromagnetic immunity

5.3.18.2.1 Immunity to radiated rf EM fields

Test methods and instruments specified in 2.5, IEC 1000-4-3 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: 80 MHz to 1 GHz;

c) 80% AM modulation, at one frequency near the geometric mean of the ECG pass band.

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

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

5.3.18.2.2 Immunity to conducted EM fields

The test methods and instruments specified in the current draft of 2.5, IEC 1000-4-6 apply.

An injected rf field as described in 4.3.18.2.2 shall be injected into the line cord. No inadvertent discharge or other unintentional change of state shall occur during this test.

5.3.18.2.3 Immunity to magnetic fields

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

a) magnetic field intensity: 80 A/m (1 gauss) peak-to-peak;

b) frequency range: 47.5 Hz to 1320 Hz.

The defibrillator is exposed on all faces. Verify that no inadvertent discharge or other unintentional change of state occurs and that stored data is not lost or corrupted.

5.3.18.2.4 Immunity to electrostatic discharge

The test method and instruments specified in 2.5, IEC 1000-4-2 apply. Verify that only transient loss of functionality occurs and that the equipment resets without operator intervention.

5.3.18.2.5 Power line transients

a) First transients/burst - The test methods and instruments of 2.5, IEC 1000-4-4 apply.

b) Surge immunity - The test methods and instruments of the current draft of 2.5, IEC 1000-4-5 apply.

5.3.19 External pacing

5.3.19.1 Pacing mode activation

Compliance with these requirements can be verified by inspection.

5.3.19.2 Pacing delivery

5.3.19.2.1 Separate pacing pathway

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

a) Compliance with these requirements can be verified by inspection.

b) Compliance with requirements 4.3.19.2.1(b) can be verified by performing the following test procedures:

1) Connect the pacer circuit to the test circuit of figure 3. A defibrillator test load of 100 Ω, or its equivalent, shall be used.

2) Charge the capacitor to 5000 V, with switch S1 in position A. Discharge is accompanied 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.

3) After 10 seconds, verify that the pacer circuit correctly displays the test signal at an amplitude at least 50% of its normal amplitude before the test.

4) After the test, the pacer circuit shall meet all performance requirements of this standard.

5) Perform the test three times with at least 30-second separation between successive discharges.

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 specified in ANSI/AAMI DF2—1996.

2. 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.

5.3.19.2.2 Combined pathway

a) Compliance with these requirements can be verified by inspection.

b) Compliance with these requirements can be verified by inspection.

c) Compliance with requirement 4.3.19.2.2 (c) can be verified by performing the tests in section 4.3.15.11 (c).

5.3.19.3 Pacing pulse shape and duration

5.3.19.3.1 Pace pulse shape and duration accuracy

a) Connect a 50-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.

5.3.19.3.2 Pace pulse duration stability

a) If the pacemaker is battery-operated, continue the pacer operation in 5.3.19.3.1 for the duration equivalent to the nominal operating time of the battery. Measure duration every 15 minutes. The duration shall not change by more than 10% from the initial reading for any measurement.

b) If the pacemaker is powered off AC-mains, continue the pacer operation in 5.3.19.3.1 for the duration equivalent to the duration of the maximum length of treatment with a given set of electrodes as specified in the operating instructions. Measure duration every 30 minutes. The duration shall not change by more than 10% from the initial reading for any measurement.

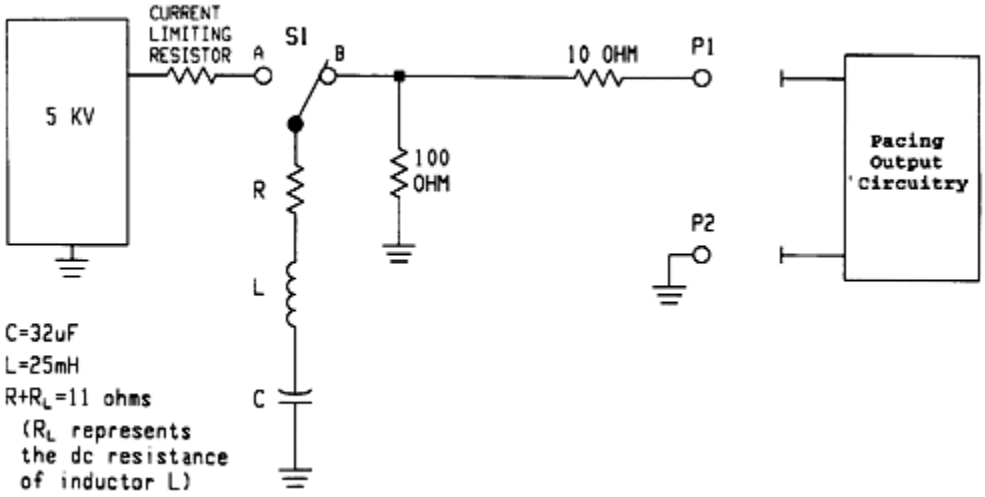

Figure 3¾ Test circuit for defibrillator overload test of pacing output circuitry

5.3.19.4 Pacing pulse current

5.3.19.4.1 Pacing pulse current accuracy

a) Perform steps a) and b) of 5.3.19.3.1.

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

5.3.19.4.2 Pacing pulse current stability

a) If the pacemaker is battery-operated, continue the pacer operation in 5.3.19.4.1 for the duration equivalent to the nominal operating time of the battery. If pacing current control is provided, it should be set to mid-range. Measure duration every 15 minutes. The current shall not change by more than 10% from the initial reading for any measurement.

b) If the pacemaker is powered off AC-mains, continue the pacer operation in 5.3.19.3.1 for the duration of the maximum length of treatment with a given set of electrodes as specified in the operating instructions. If a pacing current control is provided, it should be set to mid-range. Measure duration every 30 minutes. The current shall not change by more than 10% from the initial reading for any measurement.

5.3.19.5 Pacing rate

5.3.19.5.1 Pacing rate accuracy

a) Perform the steps a) and b) of 5.3.19.3.1.

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 shall 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 controls labeling shall be performed.

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

5.3.19.5.2 Pacing rate stability

a) If the pacemaker is battery-operated, continue the pacer operation in 5.3.19.5.1 for the duration equivalent to the nominal operating time of the battery. If a pacing rate control is provided, it should be set to mid-range. Measure duration every 15 minutes. The rate shall not change by more than 10% from initial reading for any measurement.

b) If the pacemaker is powered off AC-mains, continue the pacer operation in 5.3.19.5.1 for the duration of the maximum length of treatment with a given set of electrodes as specified in the operating instructions. If a pacing rate control is provided, it should be set to mid-range. Measure duration every 30 minutes. The rate shall not change by more than 10% from the initial reading for any measurement.

5.3.19.6 Pacing protocol

Compliance with this requirement can be verified by comparison of actual device operation to the description of the device operation provided in the operating instructions.

5.3.19.7 Demand pacing

For units with the capability of monitoring and pacing through the same set of electrodes, the ECG/pacing leads should be connected to a defibrillator tester capable of providing a 1-mV ECG signal to the pacing/ECG cable at a variable rate. For other units not capable of this multifunction operation, the ECG leads should be connected

to a simulator capable of providing an ECG signal at a variable rate. An oscilloscope probe should be placed across the inputs to the defibrillator tester to measure the pacing energy delivered into the 50-ohm load of the tester. The simulator rate should be set to 120 beats per minute (bpm), and the pacing rate of the unit should be set to 68 ppm. The unit shall not have pacing activated. Change the simulator setting to 60 bpm. The unit shall now have pacing activated.

Set the simulator to a rate of 180 bpm and the pacing rate of the unit to 134 ppm. The unit shall not have pacing activated. Change the simulator setting to 120 bpm. The unit shall now have pacing activated.

5.3.19.8 Pacer lead-off indication

Connect the pacer output cable to a 250-ohm power resistor, and pace at the maximum amplitude allowed by the unit. The unit shall not indicate that a pacer lead-off condition is present.

Set the output to 20 mA and disconnect the pacer output cable from the load resistor. The unit shall indicate that a pacer lead-off condition is present.

5.4 Requirements for physical characteristics

5.4.1 Cable length

Compliance with the requirements of 4.4.1 can be verified by inspection.

5.4.2 Paddle electrode mechanical shock resistance

This test applies only to cable-connected paddle electrodes, not to paddle electrodes integral to the defibrillator unit without cable connection. During this test, the paddle electrode cables might have to be disconnected or otherwise separated from the defibrillator unit to allow a free fall of the paddle electrode.

a) *Test set-up*. A common asphalt-tiled concrete floor at least 1 m^2, a cable-restraining device to prevent the paddle electrode from striking the cable during the fall and impact, and a 1-m benchmark are needed for this test.

b) *Procedure*.

1) Raise the paddle electrode to the 1-m benchmark, orienting it so that one of its three mutually perpendicular axes points downward, and release. Repeat with the same axis pointing upward.

2) Repeat 1) for the other two axes. Repeat the entire 1) and 2) sequence five times, for a total of 30 drops.

c) *Inspection*. Visually inspect the paddle electrode for cracks, bending, or other damage that could prevent it from meeting its operational and safety requirements. Perform functional verification as described in 5.3.

NOTE—This procedure is not recommended for routine user testing.

5.4.3 Cleaning or sterilization

Compliance with the requirements of 4.4.3 can be verified by subjecting the paddle electrodes to 50 complete cleaning or sterilization cycles in accordance with the manufacturer's instructions, and then performing all tests required by this standard with the paddle electrodes connected to the defibrillator.

NOTE—The procedure given is not recommended for routine testing.

5.4.4 Device markings

a) Inspect the device markings for compliance with the contrast and size requirements of 4.4.4.

b) 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.

c) Repeat the wiping procedure four times.

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

Annex A
(Informative)

Rationale for the development and provisions of this standard

A.1 Introduction

This appendix explains why the standard was developed and provides the rationale for each specific provision.

The first Association for the Advancement of Medical Instrumentation (AAMI) standard for cardiac defibrillators (ANSI/AAMI DF2—1981) was the product of a long developmental history that commenced in 1973 with the issue of a Food and Drug Administration (FDA) contract to the UBTL Division of the University of Utah Research Institute. Under this contract, UBTL was to develop a performance standard for cardiac defibrillator devices. In February 1977, the sixth draft of a defibrillator standard was published.

In 1978, AAMI and the FDA entered into an agreement under which the FDA/UBTL sixth draft standard would be used as the basis for a voluntary consensus standard for defibrillators. The actual development and refinement was to be undertaken by the AAMI Defibrillator Committee, with the product of that effort to be promulgation of an American National Standard.

Early in the deliberations of the AAMI Defibrillator Committee, it became apparent that it would be necessary to establish a scientific consensus on the controversial issue of the maximum deliverable energy that should be available from a defibrillator. Additionally, it was concluded that a meaningful definition of clinically proven output waveforms would have to be developed if a performance standard for defibrillators were to move forward to national consensus and acceptance and if the risks to health associated with the device (see section A.2) were to be adequately addressed. Neither maximum deliverable energy nor waveform specifications had been definitively addressed in the FDA/UBTL sixth draft, because in early 1977, a scientific consensus had not been firmly established on either issue.

Consequently, much of the AAMI committee's work during late 1978, 1979, and early 1980 was devoted to resolving these two questions in addition to a continuing refinement of other aspects of the FDA/UBTL sixth draft standard. The rationale for the provisions eventually arrived at by the committee, relative to maximum deliverable energy and output waveform definition, is provided in A.4.3.2 and A.4.3.4.

During this same interval, the FDA's Cardiovascular Device Classification Panel, a group of medical experts established to advise the agency on appropriate classifications of cardiovascular devices for purposes of regulation, had been deliberating on whether the panel's final recommendation to the FDA should be that defibrillators be regulated as Class II devices (performance standards) or Class III devices (premarket approval). In the 9 March 1979 *Federal Register*, the FDA published a rule, for public comment, that proposed to classify all defibrillators as Class III devices. The basis for this proposal, as well as a history of the panel's deliberations, was described in detail in the *Federal Register* notice. Briefly, the notice concluded that insufficient data existed to establish a performance standard that would adequately control the risks to health posed by the device; hence, a classification of Class II could not be justified for these life-sustaining devices. By the time, however, that the final classification of defibrillators was to be promulgated, the AAMI committee had established a consensus on maximum deliverable energy, and a consensus was emerging on the question of output waveform definition. Because these issues had represented two of the major concerns of the panel and the agency, the panel decided in August 1979 to recommend a reclassification of defibrillators, and the FDA concurred.

The final rule for defibrillators classified those devices having a maximum deliverable energy up to 360 joules

as Class II devices (performance standards) and those devices having maximum deliverable energies greater than 360 joules as Class III (premarket approval). It was noted in the final rule that "classification of certain defibrillators into Class II requires that standards address not only energy but other important considerations, such as paddle (electrode) size, and waveform characteristics . . ." (*Federal Register*, 5 February 1980).

The first edition of the AAMI defibrillator standard was approved and published in 1981. A second edition of the standard was published in 1989 (ANSI/AAMI DF2—1989). This third edition of the defibrillator standard was extensively revised to reflect developments in technology, features, performance, and applications.

A.2 Need for the standard

If cardiac defibrillators malfunction, the status of patients who are at high medical risk because of life-threatening arrhythmias will not improve. The delivery of excessive energy or current can damage cardiac tissue (A.4.3.2) or can result in the persistence of fibrillation. The delivery of insufficient energy or current, inappropriate waveform characteristics, inappropriate paddle electrode design, and other device-related features can result in ineffective defibrillation. Either situation can be life-threatening for the patient. Additionally, as is the case with any electrical equipment, some risk to the operator can be associated with the device use.

The risks to health identified by the FDA Advisory Panel are as follows: "a) Electrical shock to the operator: Improper electrical design of the device can lead to a serious electrical shock to the operator. b) Inability to defibrillate or persistence of the arrhythmia . . . may occur because of excessive energy, excessive current, insufficient energy, insufficient current, a difference between the indicated level of energy and the delivered level of energy, as delivered into a 50-ohm load, or excessive leakage current. c) Inability to defibrillate . . . may occur when certain drugs that can raise the defibrillation threshold are used. d) Inability to defibrillate. . . may result from inappropriate paddle (electrode) size or inappropriate paddle (electrode) location on the subject." (*Federal Register*, 9 March 1979).

Effective defibrillation is influenced by a number of factors, not all of which are device-related. The *Federal Register* notice of 9 March 1979 indicated, for example, that "many factors other than device-related properties can alter the defibrillation threshold of a patient, including the use of drugs such as lidocaine, the presence of myocardial infarction, hypoxic and acidotic conditions, and endogenously liberated substances such as adrenalin."

This standard, then, is intended to provide reasonable assurance that the device itself will perform, and can be used, safely and effectively in defibrillation procedures.

A.4 Rationale for the specific provisions of the standard

This section contains the rationale for each of the requirements of section 4 of this standard. The paragraph numbers below correspond to those of section 4.

A.4.1 Device labeling

The committee developed the requirements of 4.1 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 4.1 of this standard are intended to assure that certain specialized information, necessary for the safe and effective use of defibrillators, will be included in device labeling.

A.4.1.1 Defibrillator labeling–Control indicators–Cautionary warning notices and A.4.1.2 Battery charger labeling

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

the peak line current averaged over the 2 seconds following charge initiation so that the user will know the worst-case condition that any hospital circuit breaker must accommodate.

The use of standard notation in the labeling of controls was considered important in facilitating the rapid, error-free operation of defibrillators. The specific nomenclature chosen was based on the previous version of this standard (ANSI/AAMI DF2—1989) and agrees with the labels in current use for commercially available defibrillators. Permitted as an alternative to the methods listed for the labeling of the OFF/ON control in 3.1.1 are "other designs that clearly indicate the operating condition of the defibrillator." This option is provided to accommodate the use of, for example, the international symbols for ON and OFF specified by the International Electrotechnical Commission (1983b).

Labeling the energy indicator SELECTED ENERGY, JOULES, that is, the energy that would be delivered to a 50-ohm lead, is now universally accepted practice.

Because risks are associated with normal device operation, the committee considered it important to require that the warning notices in section 4.1.1 be displayed on the defibrillator. These warnings address the electrical shock hazard associated with the device, which is due to the high voltage, usually 3,000 to 5,000 V, that may be present on the capacitor. It was therefore considered essential that the defibrillator be used and serviced only by properly trained personnel. Also addressed is the potential explosion hazard associated with using the device in the operating room and in other environments where flammable anesthetics may be present.

The previous version of this standard (ANSI/AAMI DF2—1989) permitted a partial exemption to the energy range requirements in that defibrillators not capable of delivering at least 250 joules into a 50-ohm load were permitted if they were labeled with the appropriate warning. This partial exemption is no longer necessary, because all current defibrillators are capable of delivering at least 250 joules into a 50-ohm load.

A.4.1.3 Self-adhesive electrode labeling

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, i.e., during electrode application to a patient.

A.4.2 Operating instruction and maintenance manuals

No instrument can be operated properly without adequate instructions describing its use and controls. The information required in 4.2 is intended to ensure that sufficient instructions are available to the user for the safe and effective operation and adequate maintenance of the device.

A.4.3 Essential requirements

A.4.3.1 Operating conditions

Defibrillators must perform under a wide range of environmental conditions. It is therefore reasonable to set the requirements for operating conditions based on the intended use environment. It is also reasonable to ask disclosure in the manual of the range of other environmental conditions within which the defibrillator has been tested and performs successfully. The standard also defines a standard resistive load to facilitate performance and comparability of the test in section 5.

The previous version of this standard (ANSI/AAMI DF2—1989) specified only the operating temperature range of the operating conditions. This new revision significantly expands the operating conditions section to include humidity, atmospheric pressure, vibration, shock/drop, and enclosure protection. These conditions are included because they help characterize the use environment and are typical of the design and type-testing parameters normally used by defibrillator manufacturers.

The temperature, humidity, and atmospheric pressure limits were chosen because they reflect expected use environments and are, in some cases, comparable to IEC limits for defibrillators and medical devices. There was

substantial discussion in the committee about testing defibrillators at a very high temperature and humidity (45° C and 95% RH). There was concern about misleading operators relative to a defibrillator's capabilities and perhaps encouraging abuse of the defibrillator. There was also concern about the ability of test chambers to accurately achieve and maintain these extreme conditions. In the end the committee agreed to state the humidity range at a fixed temperature of 20° C. This should be considered a reasonable minimum, and manufacturers are free to test and disclose operating humidity conditions at higher temperatures.

The vibration and shock/drop section cites the MIL-STD-810. There was some discussion in the committee about citing IEC standards versus MIL standard. The general preference is to cite IEC standards. However, the MIL standard was chosen for the vibration and shock/drop requirements because it seems to be the one most used by defibrillator manufacturers at this time. The test categories and limits were chosen because they are reasonable minimum performance levels, and manufacturers are free to test and disclose more severe limits. For the air/helicopter transport use environment, manufacturers currently perform extensive testing, but they use different test categories and limits. Therefore, the committee decided to allow the manufacturer to choose and disclose the test category and limits for this use environment.

The enclosure protection levels are consistent with the expected hazards of each use environment.

A.4.3.2 Energy range

Studies using damped sinusoidal and trapezoidal waveform defibrillators have shown that defibrillators delivering energy in the range of 250 to 360 joules have been highly successful in eliminating ventricular fibrillation in humans over a broad range of body weight.

Pantridge et al. (1975) and Campbell et al. (1977) showed that damped sine wave defibrillators delivering "Lown" and "Pantridge" waveforms were highly successful when energy settings from 200 to 400 joules (of stored energy) were delivered to the thorax of human subjects. These units delivered 300 and 330 joules, respectively, into 50 ohms from a stored energy of 400 joules. Gascho et al. (1979a, 1979b) demonstrated that damped sine wave defibrillators storing 400 joules and delivering 12-ms pulses of the "Pantridge" type waveform and 5-ms pulses of the "Lown" and "Edmark" type waveforms were successful 95% of the time during 253 episodes of ventricular fibrillation. The maximum deliverable energy into 50 ohms for several of these defibrillators was found by Crampton to be 360 joules. Using a longer duration truncated exponential waveform (also known as the trapezoidal waveform) delivering a 250-joule pulse of energy, Anderson and Suelzer (1976) showed high clinical success in converting ventricular fibrillation to some other cardiac rhythm in 108 patients. This type of waveform was investigated extensively in animals by Schuder et al. (1966).

In addition, animal studies by Van Vleet et al. (1977) and Tacker et al. (1979) demonstrated that there is a considerable safety factor between a defibrillation shock large enough to defibrillate and a shock large enough to produce morphologic alterations in the cardiac tissue. These studies were carried out using damped sine wave and trapezoidal waveforms similar to those in the human studies of Pantridge, Gascho, and Anderson, referenced previously.

These clinical and experimental studies indicate that defibrillators that use damped sine wave or trapezoidal waveforms and that deliver energy in the range of 250 to 360 joules into 50 ohms are relatively safe and effective. Although some animal studies imply a need for higher energies, this range has been accepted by many experts as a reasonable compromise and provides reasonable assurance of device safety and efficacy in human ventricular defibrillation.

With respect to the number of energy selections defined in 4.3.2, six intermediate values were considered the minimum necessary to allow for the conventional clinical practice of doubling the selected delivered energy after each unsuccessful defibrillation attempt. Thus, if it is assumed that, for nonsynchronized defibrillation, the initial energy chosen will be the minimum defined by the standard (10 joules), six intermediate values will be needed to reach E_{MAX} (360 joules). (Defibrillation attempts are typically begun at relatively low energies to minimize the risk of myocardial damage.) Two different minimum values are defined for synchronized versus

nonsynchronized cardioversion, because clinician members of the committee did not consider 10 joules to be sufficiently low for effective synchronized defibrillation. In recent years, interest and demand for low delivered energy levels have increased, and recent defibrillators usually offer several levels below 10 joules.

The 50-joule limit on the maximum selectable delivered energy available from internal paddle electrodes was developed because of the committee's concern about the risk of myocardial damage at higher energies. Studies by Kerber et al. (1980), Tacker et al. (1978), and Rubio and Farrell (1979) showed that the vast majority of patients can be successfully defibrillated, open-chest, at energy levels below 50 joules. In the Kerber study, for example, it was concluded "that the optimal initial energy for open-chest defibrillation is 10 to 20 joules, and that this dose may be repeated if necessary. This dose will defibrillate more than 90% of hearts, and is unlikely to cause shock-induced necrosis. Smaller doses (5 joules) are less effective, whereas larger doses, especially if repeated many times, can cause myocardial necrosis." Based on these studies and on unpublished data from a University of Virginia study, the committee believes 50 joules to be a maximum upper limit for safety, one that is well above that typically needed for effective open-chest defibrillation. It is recognized that future data may reveal the need to further reduce the maximum selectable delivered energy available from internal paddle electrodes.

A.4.3.3 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 tolerance of ±15% reflects an effort to provide the best practical accuracy consistent with the present state-of-the-art in defibrillator design and energy-measuring equipment. The ±15% 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- to 100-ohm loads is ±3 joules or ±40%, whichever is greater. The allowed inaccuracy of 40% is undesirably large, but this large number is made necessary in the worst case to accommodate the ±15% 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 to 12 ohms) are available and are now commonly used. Such inductors will reduce the worst case inaccuracy to less than ±30%. A possible increase from ±3 joules to ±8 joules 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 to 20 joules) that are commonly used in internal or infant defibrillation.

A.4.3.4 Discharge waveforms

Changes to the waveform specification in the third edition generally reflect observations on waveform performance since prior editions.

The first and most apparent change is the addition of the 125-ohm specification category for all waveforms. This reflects the experience that with the trend toward defibrillation at lower voltages, at least 10% of patients now present transthoracic impedances greater than 100 ohms, the previous upper limit of the specification. The addition of the 125-ohm category encompasses almost all patients.

The second general change is the accommodation of emerging defibrillation waveform and dosing techniques (e.g., biphasic waveforms, overlapping or multiple pulses, current dosing). Because the specification is revised only infrequently, a method is provided to allow and encourage innovation of commercial devices as the science progresses. This method allows manufacturers to establish the clinical efficacy of defibrillation techniques outside the older bounds set for damped sinusoid or truncated exponential waveforms. The methodology outlined demands rigorous study design and the publication of results. The waveform parameters studied must be presented in a manner that, like the older specification, allows meaningful and accurate routine testing of commercial devices. Once proven and presented using the prescribed methodology, devices may then be offered

to the market under the umbrella of the standard.

A.4.3.4.1 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. (1975), Campbell et al. (1977), and Gascho et al. (1979a, 1979b).

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, four values of load resistance—25, 50, 100, and 125 ohms—were chosen for table 1. 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. In the third edition of the standard, however, a load resistance of 125 ohms was added to better accommodate the observed range of patient impedances.

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) to determine an acceptable waveform envelope, and then adding a tolerance band to account for the 20% component variation consistent with the state-of-the-art in the manufacture of damped sinusoidal waveform defibrillators.

In the third edition, it was recognized that the specification did not address waveform performance beyond the initial lobe and subsequent undershoot, if any. Nevertheless, improperly chosen RLC combinations can result in physiologically active current levels for considerable time, especially for high-impedance patients. Such currents are well beyond the chronaxie for defibrillation (Kroll, 1993). At longer durations, especially in highly damped circuits, RLC circuits approach exponential currents with similarities to capacitive discharges. Small, persistent currents of this type have been suspected of refibrillation phenomena (Schuder et al., 1980) and post-shock arrhythmia (Peleska, 1963). Accordingly, for waveform durations greater than 20 milliseconds, a table of maximum allowable currents (expressed as a percentage of waveform peaks) was adopted. It is of note that the original waveforms of Lown and Edmark, for which much of the published efficacy literature is based, meet the modified limits easily.

The committee elected to relax the waveform reverse current undershoot specification in view of evidence that undershoot is not detrimental to performance. Undershoot was described as a percentage of peak forward currents.

A.4.3.4.2 Monophasic truncated exponential waveform

The family of truncated exponential waveforms often referred to as Schuder waveforms has been studied extensively with animals (Schuder et al., 1980) but has not been as critically or extensively evaluated clinically as the damped sinusoidal waveform. One published study (Anderson and Suelzer, 1976) has documented the safety and efficacy of one such waveform. Other references note that defibrillators using this waveform have been employed with some field success (Bocka and Swor, 1991; Mols et al., 1994). 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, four values of load resistance—25, 50, 100, and 125 ohms—were chosen for table 2. 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_d in the standard were compared with the waveform specifications of the manufacturer of the defibrillator model referenced in a clinical study (Anderson and Suelzer, 1976) 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% component variation.

During revision for the third edition, it was noted by the committee that few experimental reports in animals favor monophasic truncated exponential waveforms with durations of longer than 20 milliseconds. Although currents required for defibrillation decline modestly as durations approach 20 milliseconds, the energy required for defibrillation climbs sharply by 40 milliseconds (Wilson et al., 1989, Gold et al., 1979). Further, waveforms beyond 20 milliseconds have declining safety margins between those currents necessary to defibrillate and those exhibiting postshock dysfunction (Jones et al., 1980). Nevertheless, no human data were available to justify limiting the waveform duration, and the maximum duration specification was left intact.

Similarly, at durations less than 3 milliseconds, energy requirements do not decrease, but current requirements are seen to increase sharply (Holmes et al., 1980), which is exacerbated by higher waveform tilts. This is further illustrated in animal studies by rapidly changing defibrillation success contour graph profiles below 3 milliseconds (Gold et al., 1979). The committee noted that specifying the minimum duration of this waveform category to at least 3 milliseconds for energies greater than 5 joules minimizes these issues and does not impair the ability of devices to deliver effective current/energy combinations.

Tilt is recognized as an important variable in defibrillation efficacy and defibrillator efficiency. In general, higher-tilt monophasic waveforms require higher initial currents for equal efficacy than do low-tilt waveforms (Holmes et al., 1980; Bourland et al., 1978). Although exact relationships between tilt and efficacy have remained unclear, it is strongly suggested that very high-tilt monophasic waveforms (which approach pure untruncated capacitive discharges) are associated with refibrillation phenomena (Schuder et al., 1980). In adopting a tilt specification, it was noted by the committee that 80% tilt represents energy delivery efficiencies of approximately 96%, and tilts above that value could do little for defibrillator design.

A.4.3.5 Pulse rate

The requirement of 4.3.5 was developed to provide assurance that a defibrillator would be able to deliver a sufficient number of pulses to guarantee that defibrillation could be accomplished in a short period of time without excessive heating or damage to the defibrillator. The requirement was relaxed for battery-powered defibrillators operating at low temperatures, because changes in battery characteristics occur at low temperatures. The requirement for four discharges of E_{MAX} in rapid succession was developed to preclude the possibility that a defibrillator could destroy itself under conditions of rapid use.

A.4.3.6 Charge time

The committee judged that a specific requirement for maximum charge time was appropriate. This specification coincides with the one cited in Clause 101 of IEC 601-2-4, *Medical electrical equipment, Part 2: Particular requirements for the safety of cardiac defibrillators and cardiac defibrillator/monitors* (IEC 1983a).

A.4.3.7 Battery capacity and shelf life

The committee judged that a specific requirement for minimum battery capacity at low temperature was appropriate. This specification coincides with Clause 102.2 of IEC 601-2-4.

The committee judged that a specific requirement for battery shelf life was appropriate. This specification coincides with Clause 102.3 of IEC 601-2-4.

A.4.3.8 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 momentary to the time (30 to 120 seconds) when automatic disarm is activated. The requirement of 4.3.8 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 within 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 one full second). Both methods are acceptable provided that 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. See also A.4.3.10.3.

A.4.3.9 Automatic disarm

A charged defibrillator is a potentially harmful device if discharged inadvertently. Hence, a device should not remain charged indefinitely, and an automatic disarm provision is required for safety. Also, keeping a defibrillator fully charged for lengthy periods will reduce the life and reliability of the high-voltage circuits, particularly in the case of lightweight, portable devices using certain types of capacitors. On the other hand, a clinician may have a defibrillator charged and ready but then require a certain time for decision-making or for optimizing the timing of the discharge based on the patient's symptoms or safety considerations.

Hence, the choice of the time at which automatic disarm is activated represents a compromise among several factors: the need to provide adequate decision-making time, the need to limit the duration of a potentially hazardous condition, and the need to ensure instrument reliability. The clinicians on the committee were unanimous in recommending that automatic disarm not be activated before a minimum of 30 seconds after completion of charge, and the committee concurred. The requirement that the actual time (within the accepted range) chosen by the manufacturer be disclosed was developed to ensure that users of the device could anticipate the time at which the desired energy would no longer be available and thus anticipate when the device would have to be recharged. To accommodate special clinical needs, particularly in the electrophysiology lab, the possibility of a much longer time period before activation of automatic disarm was explicitly allowed with an additional labeling requirement to ensure safety and minimum confusion.

Automatic disarm sometimes occurs without the clinician's being aware of it, causing confusion and concern, appearance of device malfunction, and possible harm to the patient. Hence, activation of automatic disarm must be very obvious and recognizable by the clinician. For that reason, audible indication of disarm is required, and additional visual indication is recommended.

A.4.3.10 Control 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, when 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.4.3.10.1 Operating mode indicator

The ability to easily determine the operational mode of the defibrillator is required for the efficient and safe use of the device. The absence of any indication means that the defibrillator is in the ventricular defibrillation mode. Conversely, a clear visual indication must be given if the defibrillator is in the synchronized cardioversion mode.

A.4.3.10.2 Energy 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 standardization in units that would be consistent for all types of defibrillators and energy delivery circuits.

A.4.3.10.3 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 must 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 "discharged" or "charging" indicators as well, was intended to prevent operator confusion when the operator is using an unfamiliar model in an emergency situation.

A.4.3.10.4 Low-battery-charge indicator

The basis for this requirement is the necessity for the user to determine in advance when the battery will no longer provide sufficient power to operate the defibrillator. Ideally, this warning should occur when the defibrillator is still capable of the several discharges needed for a typical defibrillation episode (for example, three). However, because many commonly used batteries exhibit a sudden rapid fall in power output when they approach complete charge depletion, advance prediction of battery depletion is very difficult. The committee therefore concluded that, as a minimum, the defibrillator should be capable of at least one additional charge and discharge at E_{MAX} after the operator is made aware of the low-battery condition. More advance warning is preferred and should be provided if technically feasible. A continuous battery-charge indication, a "push-to-test" mechanism, or other more sophisticated method may be used to satisfy the requirement of 4.3.10.4.

A.4.3.10.5 OFF/ON

The OFF/ON control must be highly visible to permit rapid location and ready interpretation by the operator. Positive actuation of the control is required so that there can be no operator uncertainty regarding the consequence of control manipulation. A control is necessary to standardize turn-on capability, although its function may be combined with another function if properly labeled.

A.4.3.10.6 Mode selection

For defibrillators capable of synchronized discharge, a clear indication of operating mode is essential to minimize response time and errors during use. The requirement for a return to normal (nonsynchronized) mode when device power is turned off or disconnected is intended to reduce the possibility that the defibrillator can inadvertently be in the synchronized mode. (A defibrillator that is inadvertently in the synchronized mode may not discharge properly during treatment of a patient in ventricular fibrillation.)

A.4.3.10.7 Charge control

The requirement that each charge cycle be manually initiated was developed to facilitate deliberate operator control of the immediate discharge potential of the defibrillator paddle electrodes. Although the committee recognized that some hazard is involved in the situation in which only one operator is present (who would have to simultaneously manipulate the paddle electrodes and manually initiate the charge), most users surveyed by UBTL felt that a greater danger was presented, even under the best conditions, when an automatic charge cycle was initiated each time the device was discharged. In this latter case, the operator is always confronted with the problem of safely manipulating paddle electrodes with an ever-present discharge potential.

A.4.3.10.8 Discharge control

For external defibrillation, safety considerations require that the operator have primary control over the discharge of the defibrillator.

A.4.3.11 Open/shorted discharge

The committee recognized that discharging the defibrillator through open or shorted paddle electrodes is not desirable, owing to the danger of electrode surface pitting, possible internal damage to the defibrillator, and risk to the operator. Because this situation does occur in use, however, the requirement of 4.3.11 was developed to

ensure that the device is adequately protected from this type of abuse. The specific requirement for 10 E_{MAX} discharges with paddle electrodes shorted and 10 E_{MAX} discharges with paddle electrodes separated in the air was added to coincide with Clause 103 of IEC 601-2-4.

A.4.3.12 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.4.3.13 Reduce-charge capability

The reduce-charge capability allows the operator to safely lower the energy of the device if it is decided that the selected energy is higher than desired; for example, if the device inadvertently has been set to E_{MAX} and a lower level is preferred for cardiac defibrillation. The 20-second specification was chosen as a reasonable period over which to accomplish the energy reduction and subsequent recharge to a lower energy level. This period generally is consistent with Clause 51.103 of IEC 601-2-4, which calls for an internal discharge time constant of less than 10 seconds.

A.4.3.14 Paddle electrodes

A.4.3.14.1 Insulation

A proposal was made to require that single fault conditions (failure of a single component, insulation barrier, or other protective means of the device) shall not result in unprovoked delivery of energy to the patient or operator. Although the design goal is desirable, it is difficult to demonstrate compliance and is clearly not amenable to user testing. Therefore, no specific requirement was added to the standard.

A.4.3.14.2 Active patient contact area

These requirements were derived directly from the *Report of the Inter-Society Commission for Heart Disease Resources on Clinical Performance Criteria—Defibrillators* (Green et al., 1973). The contact areas specified are intended to be minimum requirements. Larger electrodes may be used, if desired, to reduce current density; however, an upper limit for electrode size for optimal human defibrillation has not been established.

A.4.3.15 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. For recent applications, particularly automatic external defibrillation, it is very desirable to use self-adhesive pregelled disposable combination electrodes that perform well in the dual monitoring and defibrillation functions. Recent studies (Stults et al., 1987) also indicate that such combination electrodes may perform better than paddle electrodes for defibrillation. Hence, combination electrodes may become preferred for defibrillation, and it is appropriate in a standard for defibrillators to consider their use and to outline a few requirements for them. However, these requirements are not sufficient to adequately characterize such combination electrodes, and the committee proposes that a specific standard be developed to cover performance criteria for combination electrodes more fully.

A.4.3.15.1 AC small signal impedance

The rationale for this requirement was derived from the performance criteria in ANSI/AAMI EC12—1991, with particular attention to the provision that 5 kΩ is acceptable where skin preparation is minimal.

A.4.3.15.2 AC large signal impedance

Impedance for self-adhesive electrodes may be higher than for standard hand-held electrode paddles used with manual defibrillators. This requirement provides a reasonable limit on impedance contributed by the electrode pair during defibrillation (less than 6%).

A.4.3.15.3 Combined offset instability and internal noise

This requirement is derived from ANSI/AAMI EC12—1991, with the added recognition that cardiac monitor bandwidth is more appropriate.

A.4.3.15.4 Defibrillation overload recovery

The fundamental rationale for this requirement is consistent with ANSI/AAMI EC12—1991 and ANSI/AAMI EC13—1992. The requirement and test are stated in terms more directly applicable to defibrillators; that is, in terms of actual exposure to defibrillation energies rather than simulated DC offsets.

A.4.3.15.5 Biological response

This requirement is derived from ANSI/AAMI EC12—1991. Application to broken skin is to be avoided, therefore the requirement for intracutaneous reactivity is not applicable.

A.4.3.15.6 DC offset voltage

This requirement is unchanged from ANSI/AAMI EC12—1991. See that rationale.

A.4.3.15.7 Bias current tolerance

This requirement is unchanged from ANSI/AAMI EC12—1991. See that rationale.

A.4.3.15.8 Electrode active area

For electrodes intended for adult use, the requirements, test, and rationale are taken exactly from ANSI/AAMI DF39—1993. The 15 cm^2 requirement for individual electrodes intended for pediatric use is retained from ANSI/AAMI DF2—1989. Following the logic of DF39—1993, the pediatric requirement is extended to include a combined electrode area of three times the individual area. The committee also agreed to review the issue of pad electrode size for adults and pediatric use when the results of new studies become available.

A.4.3.15.9 Electrode adhesion and contact to patient

Good adhesion and electrical contact between the electrodes and the patient are essential for defibrillation efficiency. They must be achieved for a variety of patient and environmental conditions and maintained over an extended period of time prior to electrode use. However, test and evaluation experience indicates 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 reasoning is consistent with the committee conclusions described in ANSI/AAMI EC12—1991.

A.4.3.15.10 Packaging and shelf-life

Two conditions are considered: long-term storage in a presumably well-controlled environment and short-term transportation either from manufacturer to customer storage site or from storage site to site of use. For accelerated age testing according to the Von't Hoff rule, a Q_{10} of 2.0 may be used.

Short-term extreme conditions may be encountered during shipment from manufacturer to purchaser or during transportation with caregivers to the site of use, which could be any accident location. A duration of 12 hours, as specified in ANSI/AAMI DF39—1993, may be too short in this context. A duration of 24 hours at both extreme temperatures of –30° C and +65° C is considered more adequate.

A.4.3.15.11 Universal-function electrodes

Defibrillators may incorporate external transcutaneous pacing as either a distinct separate treatment mode or as part of a combined defibrillation/pacing/monitoring operation. Because no general performance standards exist for combination pacing/defibrillation/monitoring electrodes, the requirements define the basic minimum controls necessary to ensure safe and reliable operation.

A.4.3.15.12 Cable length

To ensure that the user has adequate cable for most purposes, minimum cable length of 2 m (80 in) was specified for those units requiring cables. Although it was recognized that a minimum cable 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.4.3.16 Electrical risk currents

Because a defibrillator is an electrically powered device, it can potentially induce fibrillation in a patient. Although defibrillators are intended for use on patients who are already fibrillating, in an emergency situation (particularly when an ECG monitor is not available) fibrillation may be erroneously assumed. In addition, after a fibrillating patient has been defibrillated, it is important to avoid the possibility that refibrillation could be induced by excessive risk currents from the defibrillator. The standard requires that defibrillators meet the requirements of the American National Standard, *Safe Current Limits for Electromedical Apparatus* (Normative Reference 2.4), except that the allowable risk current (sink and source) permitted through the external paddle electrodes is 100 microamperes per paddle electrode, and the allowable risk current permitted through the internal paddle electrodes is 50 microamperes per paddle. The rationale for the risk current limits recommended in the ANSI/AAMI standard is provided in the rationale statement that accompanies that standard.

With respect to the allowable paddle electrode risk current for external paddle electrodes, the committee judged that a 100-microampere limit would be acceptable for the following reasons:

a) External electrodes do not come into direct contact with the heart.

b) The large electrode area provides a substantial safety factor based on the data of Watson and Wright (1973).

c) It is difficult to design coiled-cord defibrillator cables whose distributed capacitance is small enough to produce significantly less leakage.

For internal paddle electrodes, the committee judged that 50 microamperes was an acceptable maximum limit on risk current for the following reasons:

a) Risk current at 50 microamperes is not a hazard to the patient, because published medical studies (Roy, Scott, and Park, 1977; Starmer and Whalen, 1973) show that current in excess of 50 microamperes is required to initiate fibrillation, even in the extreme case of submillimeter contact electrode dimensions. The fibrillation current threshold increases with electrode contact area, which may range from 10 to 40 cm^2 for defibrillator internal paddles.

b) Unlikely fault conditions would have to be present for the patient to be exposed to any risk, even at high leakage current levels.

c) A maximum limit lower than 50 microamperes would place severe constraints on defibrillator design and performance by preventing such safety and practical features as shielded cables, adequate cable length, and location of controls at the paddle electrodes.

d) The 50-microampere limitation (at 120 V) is consistent with the limitation set in the IEC 601-2-4.

A.4.3.17 Synchronized discharge

The use of electrical energy to convert cardiac arrhythmias other than ventricular fibrillation (for example, atrial flutter, atrial fibrillation, or ventricular tachycardia) is called cardioversion. Most defibrillators are designed to be used for both defibrillation and cardioversion. In cardioversion, R waves are present in the ECG, and the discharge must be synchronized with the R wave to avoid triggering ventricular fibrillation by accidental timing of the discharge during the vulnerable period of the ventricles. Proper performance of synchronized cardioversion requires the use of a monitor and monitor leads or self-adhesive combination monitor-defibrillator electrodes.

This vulnerable period occurs during repolarization of the ventricles; it usually begins 30 to 40 ms before the apex of the T wave and ends near the apex of the T wave (DeSilva et al., 1980). If ventricular ischemia is present, the vulnerable period starts approximately at the same time but may persist for as long as 120 ms after the end of the T wave. In all cases, therefore, the onset of the vulnerable period follows the peak of the R wave by an amount of time that depends on heart rate and on the form of the ECG trace and ranges from approximately 220 ms at a heart rate of 60 beats per minute (bpm) to 120 ms at 120 bpm and as low as 100 ms at 150 bpm. The defibrillator discharge should be completed before the onset of the vulnerable period. Hence, to provide an additional safety margin and to allow for experimental inaccuracies, a maximum delay of 60 ms is specified between the peak of the R wave and the peak of the discharge. More specifically, a maximum delay of 25 ms is specified between the most recent monitor synchronizing signal and the peak of the discharge. Shorter delays are safe and readily achieved with current technology.

There was a great deal of concern about potential problems associated with the use of a separate defibrillator and monitor to perform synchronized cardioversion. The general consensus was that an integrated defibrillator-monitor combination is preferred. However, the committee recognized that such integrated instruments are not available everywhere, and a separate defibrillator and monitor will inevitably be used in many instances. In such cases, the committee felt that the operator is responsible for exercising proper care and for ensuring that the two instruments are properly interfaced and satisfy the timing requirements for safe synchronized cardioversion.

A.4.3.18 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 in which one instrument emits radiation that interferes with the performance of another instrument. EMC therefore must be considered, in the expectation that compliance with EMC standards for both emission and immunity will minimize detrimental interference between instruments.

In addition, defibrillators are often used out of the hospital in environments that vary greatly and may challenge the immunity of the defibrillator to external electromagnetic fields. For these reasons, EMC has become an important issue.

EMC performance and validation tests are very complex and require sophisticated instrumentation. It is not practical to make the defibrillator 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 that specify in detail the appropriate EMC test methods and instruments. Two of these documents are still in draft stage and therefore, 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 IEC standards have been adjusted to the specific device being considered, i.e., defibrillators, 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 defibrillators, where the patient cables act as antennas that both emit and receive rf signals and with an antenna gain that 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 the condition that the reduced immunity levels are measured and disclosed by the manufacturer.

For immunity measurements, the cables and self-adhesive electrodes (pads) are required to be terminated in a load that 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 (150 cm^2 total) used in defibrillators, the load simulating the patient should have a much smaller resistance and a much larger capacitance. Values of 1 kohm and 1 μF are recommended, even though the optimum values are not precisely known and may vary from one situation to another.

For defibrillators, the following four possible operating modes can be distinguished:

a) monitoring;

b) charging to defibrillate or cardiovert;

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 the committee believes 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 seconds for some defibrillators). Hence, the committee 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 design state-of-the-art and the almost infinite variety of EM environments that a portable device may encounter. The general CISPR and IEC documents that are referenced standardize 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), and it is important to indicate the performance of the instrument in a level 3 environment.

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

A.4.3.19 External pacing

A defibrillator 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. No consensus has been reached on the waveform characteristics providing greatest efficacy due to patent infringement issues

and other legal concerns. Therefore, rather than requiring conformance to a specific pacing waveform shape, the standard specifies that the manufacturer should make available clinical test data to demonstrate efficacy of the device with regard to pacing. Except for this area of waveform characteristics, specific requirements are made in this standard with regard to pacing labeling, controls, indicators, and operation.

This standard includes a section on pacing stability. In the clinical setting, capture is determined empirically; in addition, the patient may be left unattended while external pacing is in progress. Therefore, absolute accuracy is not as important as stability when there is the potential that capture may be lost if the amplitude, rate, or waveform duration decreases over the length of time the patient is being paced.

This standard also includes a section on pacing leads-off indication. In the clinical setting, the leads-off indicator is important, because failure of either the pacing leads or of electrode/patient contact will result in no pacing current being delivered to the patient. While there are other component failures that may also result in this condition, improper connection or electrode placement is common enough that a clear indication needs to be provided to the clinician of the viability of the pacing electrical connection.

A.4.4 Physical characteristics

A.4.4.1 Cable length

To ensure that the user has adequate cable for most purposes, a minimum cable length of 2 m (80 in) was specified for those units requiring cables. 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.4.4.2 Paddle electrode mechanical shock resistance

Paddle electrode assemblies are the most handled parts of the defibrillator system. They are dropped to the floor, banged against cabinets and other equipment, and generally mistreated. Therefore, the committee judged it necessary to require that paddle electrodes be shock-resistant. The wide variety of paddle electrode shapes, materials, and weights did not permit specification of a standard shock value. Consequently, a practical drop test, representing a worst-case situation, was devised for inclusion in the standard.

A.4.4.3 Cleaning or sterilization

To ensure that the safety and performance characteristics of the paddle electrodes would be maintained after a reasonable number of cleanings or sterilizations, the committee developed the requirements of 4.4.3.

A.4.4.4 Device markings

The committee developed the requirements of 4.4.4 to ensure that device markings would remain legible under ordinary conditions of use and that important notices would be readily visible.

Annex B
(informative)

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