

American National Standard

ANSI/AAMI PAC49:1993/(R)2000

Pacemaker emergency intervention system

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Association for the
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McKenna & Cuneo, L.L.P.
1900 K Street, N.W.
Washington, DC 20006
Attn: Jacqueline A. Henson, Esq.
Phone: (202) 496-7500

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Developed by
Association for the Advancement of Medical Instrumentation

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American National Standards Institute

Abstract:

This standard specifies labeling and performance requirements for a pacemaker emergency intervention system (EIS), which consists of a magnet and a bradycardia pacemaker. When a pacemaker conforming to PAC49, *Pacemaker emergency intervention system*, is perceived to be operating in a nonstandard way, or in a way that is not understood by the examiner, the magnet can be used to reprogram the pacemaker to a standard mode, as specified by PAC49. An EIS is intended to be used in emergency rooms, clinics, or other medical locations where a physician skilled in pacemakers is not immediately available. Follow-up to use of the EIS should always occur so that the pacemaker can be reprogrammed to an optimum setting by a physician skilled in the use of pacemakers.

Association for the Advancement of Medical Instrumentation

AAMI Pacemaker Committee

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

The AAMI **Pacemaker Committee** has the following members:

Cochairs: Bernard H. Boal, MD
 Ross Fletcher, MD
 Charles Sidebottom

Members: Bernard H. Boal, MD, Catholic Medical Center, Jamaica, NY
 David Daly, FDA/CDRH
 Doris J. W. Escher, MD, Montefiore Medical Center, Bronx, NY
 Ross Fletcher, MD, VA Hospital Medical Center, Washington, DC
 Gloria Gross, RN, CCRN
 Curtis F. Holmes, PhD, Wilson Greatbatch, Ltd.
 John Houge, Century City Hospital, Los Angeles, CA
 Nir Kossovsky, MD, UCLA Medical Center, Los Angeles, CA
 Allan Miyoshi, Siemens Pacesetter, Inc.
 Victor Parsonnet, MD, Newark Beth Israel Medical Center
 James Putzke, Eli Lilly & Company
 Kay Rutishauser, RN, AACN

Douglas Schlam, Telectronics Pacing Systems
Robert Schnitzler, MD, San Antonio, TX
Charles Sidebottom, Medtronic, Inc.
Kok-Swang Tan, PhD, Bureau of Radiation and Medical Devices,
Canada

Alternates: Robert C. Flink, Medtronic, Inc.
Tom Hogg, Siemens Pacesetter, Inc.
Daniel Huntwork, Cardiac Pacemakers, Inc.
William Midgett, FDA/CDRH
Mitchell J. Shein, FDA/CDRH

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.

Acknowledgments

The committee wishes to acknowledge the contributions of former committee member Wilson Greatbatch for his efforts in the early stages of development of this standard. The committee also wishes to acknowledge Russell Stinebring of Greatbatch, Gen-Aid, Ltd., who greatly participated in the development of this standard.

Foreword

This voluntary standard was developed by the AAMI Pacemaker Committee. This standard is intended to apply to a system that facilitates the emergency conversion of a conforming implanted bradycardia cardiac pacemaker (i.e., a pacemaker that has been designed to meet the performance requirements of this standard) to a simple standard operating mode.

The pacemaker emergency intervention system (EIS) is intended for use in emergency rooms in hospitals or clinics where a competent attendant is on duty, but who might not have the broad expertise or equipment to handle pacemaker problems. The system is intended to temporarily change the pacemaker to a simple operating mode (e.g., VVI or VOO) until a conventional pacemaker programmer can be procured or until facilities or pacemaker-trained personnel become available for proper programming or other corrective actions. Nonconforming pacemakers, which do not contain this response capability, will not respond with the EIS emergency modes when the magnetic pulse code is applied, but could respond with the manufacturer's magnet mode while the magnet is in place.

Although this standard cannot require users to take particular actions, it is hoped that the EIS magnet assembly covered by this standard will be placed in a prominent location, so that it is readily available when needed. Clear, step-by-step instructions must be included as an integral label on the magnet assembly in order to increase the utility of the system covered by this standard.

Until such time as all American pacemakers are manufactured to accept the emergency inputs specified in the pacemaker emergency intervention system standard (ANSI/AAMI PAC49—1993), simple, nonpulsed application of the EIS magnet will permit emergency conversion of most existing and future pacemakers to manufacturer's magnet mode (VOO).

This standard reflects the conscientious efforts of those substantially concerned with its scope and provisions to develop a standard for those performance levels that could be reasonably achieved at the present 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 undesirable 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 for those situations which cannot be otherwise, as in the example "Monday must follow Sunday."

Suggestions for improving this standard are invited. Comments and/or suggested revisions should be sent to AAMI, 3300 Washington Boulevard, Suite 400, Arlington, VA 22201.

NOTE—This foreword is not part of the American National Standard, *Pacemaker emergency intervention system*, ANSI/AAMI PAC49—1993.

Pacemaker emergency intervention system

1 Scope

1.1 General

This standard covers labeling and performance requirements for a pacemaker emergency intervention system (EIS). The EIS is intended for use in hospitals and clinic emergency rooms to permit conversion of conforming implanted bradycardia cardiac pacemakers to a standard high output mode (e.g., VVI, VOO) when the pacemaker is perceived by the examiner to be operating in a nonstandard way or in a way not understood by the examiner. The EIS consists of a conforming bradycardia pacemaker and an annular magnet unit that has the capability to actuate circuits within the pacemaker, thereby changing functions to a simple standard mode of operation. A conforming pacemaker is one that has been designed to meet the performance requirements of this standard regardless of any other features or capabilities. Because the EIS uses a permanent magnetic field as the actuating medium, it requires no external power or batteries and is, therefore, passive.

A section containing referee test methods is included in this standard to define the methodology by which compliance with the requirements can be verified. These test methods are designed and intended for use primarily by manufacturers.

1.2 Inclusions

Included within the scope of this standard are emergency intervention system features of implantable bradycardia pacemakers as well as the magnet and magnetic wall-hanging plate (components of the EIS).

1.3 Exclusions

Excluded from the scope of this standard are all non-EIS-related features of implantable bradycardia pacemakers.

2 Definitions

For the purpose of this standard the following definitions apply.

2.1 A-V sequential mode, asynchronous (DOO): Mode in which the atrial and ventricular sensing functions are disabled or absent; the pulse generator provides atrial pacing at the basic rate. At the end of the specified A-V interval after each atrial pulse, a ventricular pulse is provided independent of the activity of the heart.

2.2 conforming pacemaker: An implanted bradycardia cardiac pacemaker that meets the performance requirements of this standard. It responds to the entry and exit codes described in this standard.

2.3 emergency asynchronous mode (VOO/AOO): The mode that pacemakers change to when the magnet is applied and left in place subsequent to programming to the emergency inhibited mode in accordance with this standard. (High energy output continues.)

2.4 emergency inhibited mode (VVI/AAI): The mode that pacemakers change to when the entry code