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American National Standard

ANSI/AAMI PAC49:1993/(R)2000

Pacemaker emergency intervention system

AAMI Association for the Advancement of Medical Instrumentation

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PAC49 Pacemaker Emergency Intervention System

Pacemaker emergency intervention system

American National Standard

ANSI/AAMI PAC49—1993

Pacemaker emergency intervention system

Developed by
Association for the Advancement of Medical Instrumentation

Approved 16 September 1993 and Reaffirmed 14 November 2000 by
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:

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

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

described in this standard is applied. (High energy output continues.)

2.5 entry/exit code: The entry code shall consist of: (a) application of the magnet for 3 ± 1 seconds; (b) removal of the magnet for 2 ± 1 seconds; (c) application of the magnet for 3 ± 1 seconds; (d) removal of the magnet for 2 ± 1 seconds; (e) application of the magnet for 3 ± 1 seconds; (f) removal of the magnet.

2.6 escape interval: Time between a sensed beat or a pulse and the succeeding nontriggered pulse of a pulse generator.

2.7 manufacturer's magnet mode: The mode that pacemakers in programmed mode revert to when the magnet is applied and left in place.

2.8 nonconforming pacemaker: An implanted bradycardia cardiac pacemaker that does not meet the performance requirements of this standard.

NOTE—It may, however, respond with the manufacturer's magnet mode described in 4.3.2.

2.9 programmed mode: The mode that a pacemaker has been programmed to by the programmer that is appropriate for the pacemaker model in use. This is the operating mode of the pacemaker when it has not been switched to the manufacturer's magnet mode by application of a magnet, or to one of the emergency modes defined in this standard.

2.10 ventricular asynchronous (VOO): A pacemaker mode in which the atrial functions and ventricular sensing are disabled. A ventricular pulse is provided at the basic rate independent of the activity of the heart.

2.11 ventricular inhibited (VVI): A pacemaker mode in which the atrial functions are disabled or absent. If the ventricular sensing function detects a beat interval shorter than the escape interval, then the pulse generator suppresses ventricular pacing. If no ventricular beat is sensed during the escape interval, then the pulse generator provides ventricular pacing at the basic rate.

3 Essential requirements

3.1 Labeling requirements

Each magnet assembly and magnetic wall-hanging plate of the emergency intervention system shall have an attached label (for example see figure 1). The label shall carry the following note (the note shall include all text within the quotes opening at "NOTE" and closing after "defibrillators" as well as the entry code diagram [see figure 2]):

"NOTE—

"For nonconforming pacemakers: Applying and keeping the EIS magnet in place will activate the manufacturer's magnet mode in most cases.

"For conforming pacemakers: Applying and keeping the EIS magnet in place will activate the manufacturer's magnet mode.

"To activate the *emergency inhibited mode,* the EIS magnet must be applied with the correct entry code: [Entry code diagram to be inserted here; see figure 2, next page.]

"The *emergency asynchronous mode* can only be activated from the emergency inhibited mode. To activate the emergency asynchronous mode, apply and keep the EIS magnet in place.

"NOTE—The emergency mode remains activated until the exit code, which is identical to the entry code above, is applied or an appropriate programmer is used.

"WARNING—The EIS entry code is not intended for use with implantable cardioverter defibrillators."

The magnetic wall-hanging plate shall also have a label stating that when the magnet is not in use, the magnet shall be placed on the wall plate (see figure 3, page 4).

3.1.1 Instruction manual

The instruction manual for a conforming pacemaker shall identify the pacemaker as conforming to this standard, and shall provide adequate directions for use. At a minimum, the manual should include the information provided under the note for conforming pacemakers in 3.1 of this standard.

3.2 Magnet unit assembly requirements

3.2.1 Annular magnet assembly

The EIS magnet shall consist of an annular magnet 10 ± 1 cm in outside diameter having a minimum magnetic field strength of 100 gauss (10 millitesla) at a minimum distance of 2 cm from the face of the magnet assembly on the axis of the magnet.

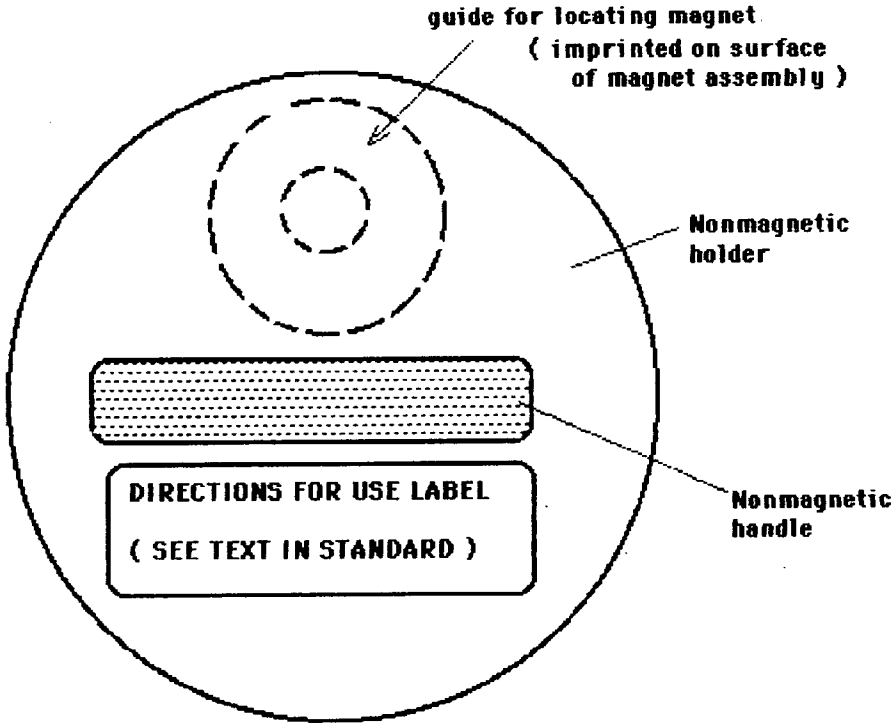

Figure 1—Top view of magnet assembly for the pacemaker emergency intervention system

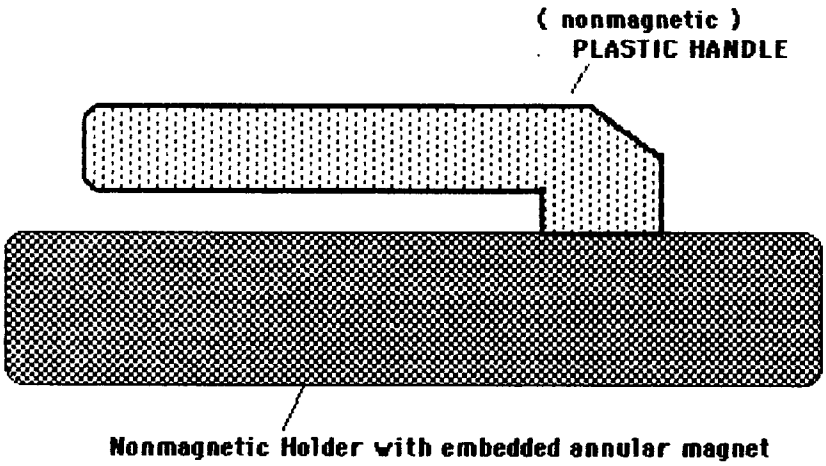

Figure 1.A—Side view of magnet assembly for the pacemaker emergency intervention system

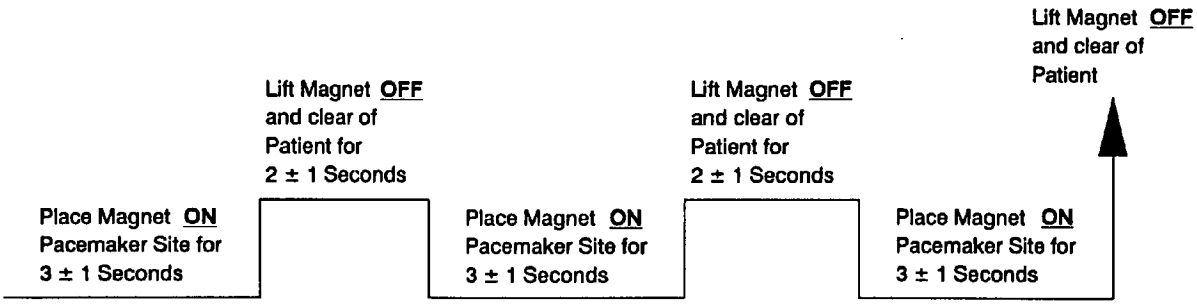

Figure 2—Entry code

The magnet shall be mounted offset (see figure 4) in a nonmagnetic holder consisting of a red plastic encapsulant approximately 20 cm in diameter and 2 cm in thickness. The location of the magnet within the assembly shall be shown by a sketch on the top surface of the assembly.

The magnet assembly shall have an attached handle that will not interfere with the field produced by the magnet (see figure 1.A).

3.2.2 Magnetic wall-hanging plate

The magnetic wall-hanging plate shall consist of a magnetic material (such as a magnetic brand of sheet steel) that can be fastened to the wall in an obvious location. The plate should be approximately 50 cm in length by 40 cm wide by 2 mm thick. This plate should also be black with white labels.

3.3 Conforming pacemaker performance requirements

3.3.1 Emergency modes

The following emergency modes shall be available:

a) emergency inhibited mode;

b) emergency asynchronous mode.

NOTE—High energy output shall be that as defined by each manufacturer, in collaboration with its own medical consultants.

3.3.1.1 Emergency inhibited mode

3.3.1.1.1 When the entry code described in 3.3.3 is applied to a pacemaker operating in the programmed mode, the pacemaker shall enter the emergency inhibited mode. It shall have a high energy output as determined appropriate by the manufacturer. The base rate of the pacemaker shall be 60 ± 1 ppm. In this mode, the pacemaker responds to intrinsic ventricular activity.

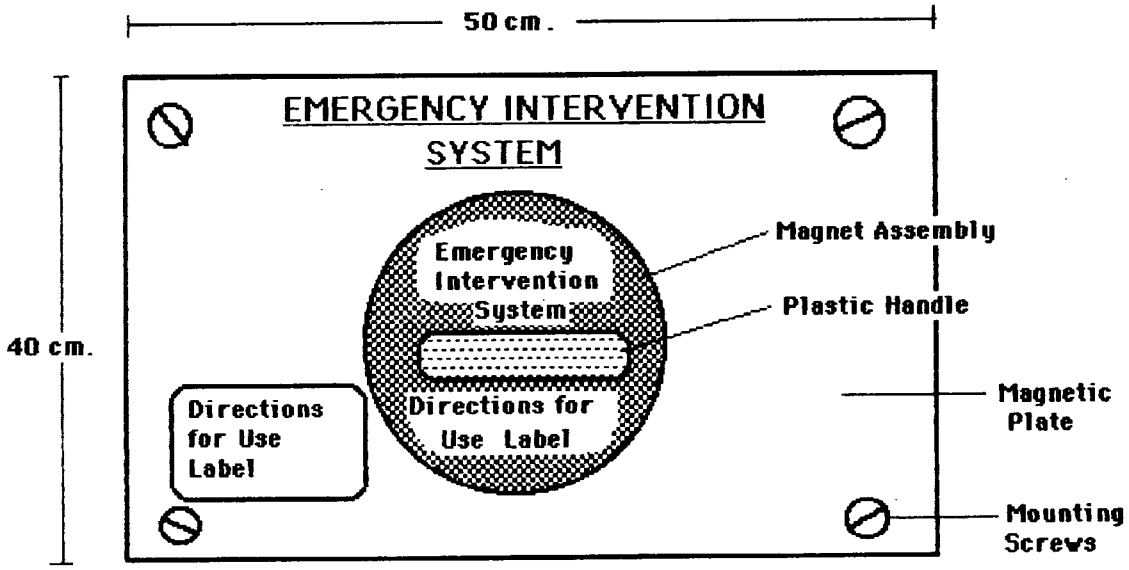

Figure 3—Schematic of emergency intervention system showing magnet assembly attached to magnetic wall-hanging plate

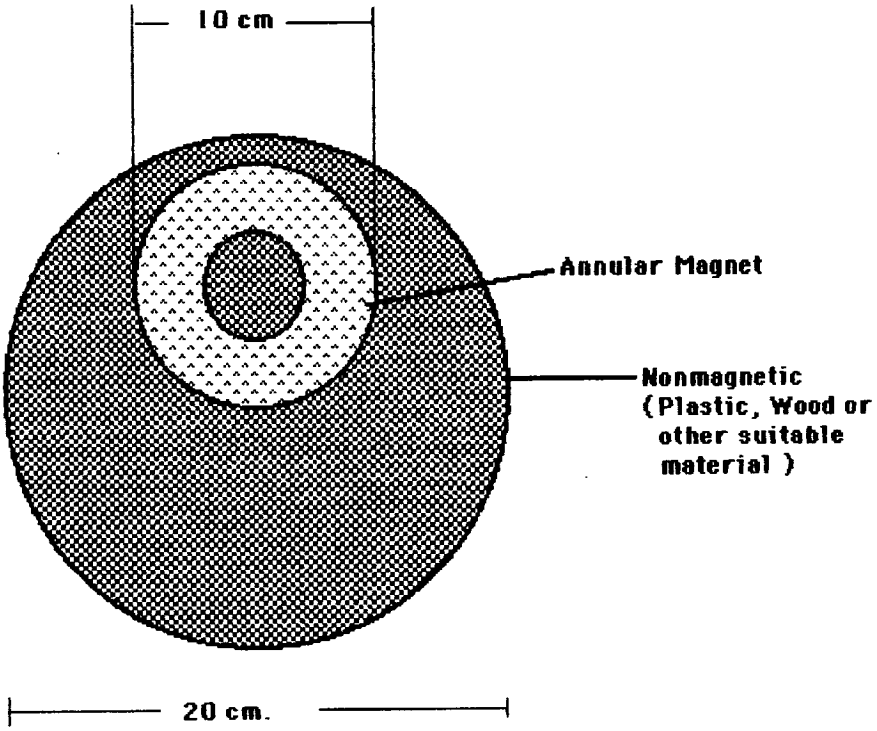

Figure 4—Bottom view of emergency intervention system magnet assembly disc

3.3.1.1.2 When the exit code described in 3.3.4 is applied to a pacemaker operating in the emergency inhibited mode, it shall return to the programmed mode.

3.3.1.1.3 Any error in implementing the entry code shall result in reversion to the programmed mode when the magnet is removed.

3.3.1.1.4 Any error in implementing the exit code shall result in reversion to the emergency inhibited mode when the magnet is removed.

3.3.1.2 Emergency asynchronous mode

When the EIS magnet is applied to a pacemaker operating in the emergency inhibited mode, the pacemaker

shall enter the emergency asynchronous mode. It shall have a high energy output as determined appropriate by the manufacturer. The base rate shall be 60 ± 1 ppm. In this mode, the pacemaker shall not respond to the intrinsic ventricular activity. The magnet must be left in position to sustain this mode. When the magnet is removed, the pacemaker shall revert to the emergency inhibited mode.

3.3.2 Manufacturer's magnet mode (VOO or DOO)

Application of the magnet when the pacemaker is in the programmed mode shall result in the manufacturer's magnet mode at programmed output, as long as the magnet is present. Upon removal of the magnet, the pacemaker shall revert back to the programmed mode. Pacemaker rate shall be defined by the manufacturer and shall not respond to intrinsic atrial or ventricular activity.

3.3.3 Entry code

The entry code shall consist of:

a) application of the magnet for 3 ± 1 seconds;

b) removal of the magnet for 2 ± 1 seconds;

c) application of the magnet for 3 ± 1 seconds;

d) removal of the magnet for 2 ± 1 seconds;

e) application of the magnet for 3 ± 1 seconds;

f) removal of the magnet.

(See also figure 2.)

3.3.4 Exit code

The exit code shall be identical to the entry code.

4 Test section

4.1 Labeling requirements

Compliance with the labeling requirements in 3.1 can be verified by inspection.

4.1.1 Instruction manual

Compliance with the requirement in 3.1.1 can be verified by inspection.

4.2 Magnet unit assembly requirements

4.2.1 Annular magnet assembly

The strength of the magnetic field at the center of the magnet shall be measured using a gauss meter positioned at a minimum distance of 2 cm from the face of the magnet assembly on the axis of the magnet.

Compliance with all other requirements shall be verified by inspection.

4.2.2 Magnetic wall-hanging plate

Compliance with the requirements in 3.2.2 can be verified by inspection.

4.3 Conforming pacemaker performance requirements

Compliance with the performance requirements in 3.3 can be verified with the following tests.

4.3.1 Emergency modes

4.3.1.1 Emergency inhibited mode

4.3.1.1.1 Enter emergency inhibited mode

a) Put the pacemaker in a programmed mode different from the emergency inhibited mode;

b) Place the pacemaker in a flat position on a nonmagnetic surface;

c) Place a 2-cm thick nonmagnetic spacer over the pacemaker surface;

d) Bring the EIS magnet into contact with the spacer covering the pacemaker and maintain contact for 3 seconds;

e) Lift the magnet assembly away from the pacemaker for a period of 2 seconds;

f) Repeat steps (d) and (e);

g) Bring the magnet assembly into contact with the spacer (for the third time) for a period of 3 seconds. Lift away the magnet assembly;

h) Measure the pacemaker ventricular output pulse and verify that it conforms to the specifications of the manufacturer for the emergency inhibited mode;

i) Measure the ventricular rate and verify that it is 60 ± 1 pulse per minute;

j) Apply a test signal as specified by the manufacturer for evaluating sensitivity and verify that the pacemaker will inhibit in the presence of a ventricular beat;

k) For dual chamber pacemakers, verify that the atrial output pulse is not present;

l) Repeat for each programmed mode available, VVI, DDD, etc.

4.3.1.1.2 Exiting emergency inhibited mode

a) Put the pacemaker in the emergency inhibited mode;

b) Place a pacemaker in a flat position on a nonmagnetic surface;

c) Place a 2-cm thick, nonmagnetic spacer over the pacemaker surface;

d) Bring the EIS magnet into contact with the spacer covering the pacemaker and maintain contact for 3 seconds;

e) Lift the magnet assembly away from the pacemaker for a period of 2 seconds;

f) Repeat steps (d) and (e);

g) Bring the magnet assembly into contact with the spacer (for the third time) for a period of 3 seconds. Lift away the magnet assembly;

h) Verify that the pacemaker has returned to its programmed mode.

4.3.1.1.3 Error in emergency inhibited mode activation

a) Test with entry code error after first magnet application

1) Place a pacemaker in a flat position on a nonmagnetic surface;

2) Place a 2-cm thick, nonmagnetic spacer over the pacemaker surface;

3) Bring the EIS magnet into contact with the spacer covering the pacemaker and maintain contact for 3 seconds;

4) Lift the magnet assembly away from the pacemaker;

5) Verify that the pacemaker reverts to its programmed mode.

b) Test with entry code error after second magnet application

1) Bring the EIS magnet into contact with the spacer covering the pacemaker and maintain contact for 3 seconds;

2) Lift the magnet assembly away from the pacemaker for a period of 2 seconds;

3) Bring the magnet assembly into contact with the spacer for a period of 3 seconds. Lift away the magnetic assembly;

4) Verify that the pacemaker reverts to its programmed mode.

c) Test with entry code error during third magnet application

1) Repeat steps (b.1) through (b.3);

2) Keep the magnet assembly away from the pacemaker for a period of 2 seconds;

3) Bring the EIS magnet assembly into contact with the spacer (for the third time) for a period of 1 second. Lift away the magnet assembly;

4) Verify that the pacemaker reverts to its programmed mode.

4.3.1.1.4 Error in exiting from emergency inhibited mode

a) Procedure

1) Program the pacemaker to a mode of operation other than VVI;

2) Place the pacemaker in a flat position on a nonmagnetic surface;

3) Place a 2-cm thick, nonmagnetic spacer over the pacemaker surface;

4) Use the magnet to activate the emergency inhibited mode.

b) Test with exit code error after first magnet application

1) Bring the EIS magnet into contact with the spacer covering the pacemaker and maintain contact for 3 seconds;

2) Lift the magnet assembly away from the pacemaker;

3) Verify that the pacemaker reverts to emergency inhibited mode.

c) Test with exit code error after second magnet application

1) Bring the EIS magnet into contact with the spacer covering the pacemaker and maintain contact for 3 seconds;

2) Lift the magnet assembly away from the pacemaker for a period of 2 seconds;

3) Bring the magnet assembly into contact with the spacer for a period of 3 seconds. Lift away the magnet assembly;

4) Verify that the pacemaker reverts to emergency inhibited mode.

d) Test with exit code error during third magnet application

1) Bring the EIS magnet into contact with the spacer covering the pacemaker and maintain contact

for 3 seconds;

2) Lift the magnet assembly away from the pacemaker for a period of 2 seconds;

3) Repeat steps (1) and (2);

4) Bring the magnet assembly into contact with the spacer (for the third time) for a period of 1 second. Lift away the magnet assembly;

5) Verify that the pacemaker reverts to emergency inhibited mode.

4.3.1.2 Emergency asynchronous mode

a) While in the emergency inhibited mode, bring the magnet assembly into contact with the plastic spacer;

b) Measure the pacemaker output pulse and verify that it conforms to the specifications of the manufacturer for the emergency asynchronous mode;

c) Measure the rate and verify that it is 60 ± 1 pulses per minute;

d) Apply a 10 mV 40-millisecond (ms) wide square pulse to the pacemaker and verify that its output is not inhibited. Apply this signal to one or both channels as appropriate.

4.3.2 Manufacturer's magnet mode (VOO OR DOO)

a) Place a conforming pacemaker in a flat position on a nonmagnetic surface;

b) Place a 2-cm thick spacer over the pacemaker surface;

c) Hold the EIS magnet into contact with the plastic spacer covering the pacemaker and maintain contact;

d) Measure the pacemaker output pulse and verify that it conforms to the specifications of the manufacturer for the manufacturer's magnet mode;

e) Measure the rate and verify that it is as specified by the manufacturer for the manufacturer's magnet mode;

f) Apply a 10 mV 40 ms-wide square pulse to the pacemaker and verify that its output is not inhibited. Apply this signal to one or both channels as appropriate.

4.3.3 Entry code

No further test is required for 3.3.3.

4.3.4 Exit code

No further test is required for 3.3.4.

Annex A
(informative)

Rationale for the provisions and requirements of this standard

A.1 Introduction

The original rationale for emergency reprogramming of implanted cardiac pacemakers dates to 1979-1980 when programmable pacemakers, each with its own manufacturer and sometimes model-specific programmer, proliferated, making access to all appropriate programmers logistically, economically, and educationally impossible.

The argument, then, was for a universal system that might be software coded to each manufacturer and model, but employ a single piece of programming hardware, limiting the need for redundancy. When this was determined to hamper freedom of innovation and development, attention immediately turned to the emergency system that is the subject of this standard.

Thus, the EIS addresses immediately the 50 percent of pacemaker malfunctions initiated by loss of pacing threshold or oversensing that can be corrected by temporary reprogramming to high output (with VVI) or elimination of sensing (VOO). This system is intended to serve only until specific equipment and knowledgeable personnel can effect appropriate long-term reprogramming. It will not affect major lead- or pulse-generator failure or any situation where the only solution is revision or replacement of a part or all of the pacing system.

A second and major rationale has resulted from the more recent development of new sensors and their algorithms, making it difficult, even for an expert, to know from the paced electrocardiogram whether the pacemaker is acting normally, or is exhibiting a reprogrammable variant, or a malfunction requiring early intervention. Emergency temporary reprogramming to high output VVI or VOO immediately establishes whether pacing is possible, and if not, facilitates the decision of whether to initiate temporary emergency pacing or to hold on until more expert help arrives.

A.3.1 Labeling requirements

The system will be used in emergency situations such as the emergency room where attendants on duty might not be familiar with pacemaker programming. Therefore, step-by-step labeling will be necessary for them to correctly operate the system.

A.3.2 Magnet unit assembly requirements

A.3.2.1 Annular magnet assembly

The magnetic field strength of 100 gauss is based on what current programmers are using. The dimensions of the holder were chosen so that it would be large enough not to fit in a pocket and be easily removed, and also so that it would be easily readable.

The magnet size of 10 cm was chosen because that is the size currently used by programmers.

The handle is nonmagnetic so that it will not interfere with the field produced by the magnet.

The color red was chosen because it is associated with devices used in emergency situations.

A.3.2.2 Magnetic wall-hanging plate

The dimensions chosen are for reference only. They were chosen because the committee deemed that they were appropriate for the apparatus to be readily visible from distances across a room.

A.3.3 Conforming pacemaker performance requirements

A.3.3.1 Emergency modes

Frequently, patients come to emergency rooms with pacemakers which appear, to the less pacing-trained emergency personnel, to be malfunctioning. One reason for the apparent malfunction could be failure to capture or oversensing. The other reason for the apparent malfunction could be the inability of the inexperienced emergency personnel to recognize the normal operation of a complex pacemaker.

Both of these reasons are dealt with by the emergency modes identified in this standard. The emergency inhibited mode provides for increased output to increase the probability of capture. The emergency asynchronous mode would determine whether sensing problems exist. Both modes provide for simple, understandable operation, addressing the problem of an examiner's failure to recognize the normal operation

of a complex pacemaker.

A.3.3.2 Manufacturer's magnet mode (VOO OR DOO)

This mode was provided because it has historically been available in pacemakers.

A.3.3.3 - A.3.3.4 Entry and exit codes

The entry and exit codes were selected because of ease of application and because the code sequence would not occur in the normal course of daily activities.