



Memorandum

Date OCT 11 1996

From Director, Office of Device Evaluation (HFZ-400)
Center for Devices and Radiological Health (CDRH)

Subject Premarket Approval of Biotronik, Inc.
Dromos DR/DR-A and Dromos SR/SR-B Cardiac Pacing Systems - ACTION

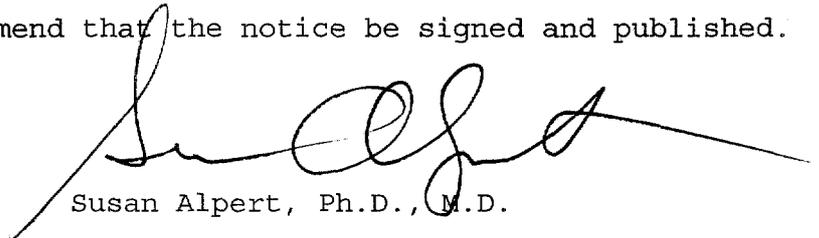
To The Director, CDRH
ORA _____

ISSUE. Publication of a notice announcing approval of the subject PMA.

FACTS. Tab A contains a FEDERAL REGISTER notice announcing:

- (1) a premarket approval order for the above referenced medical device (Tab B); and
- (2) the availability of a summary of safety and effectiveness data for the device (Tab C).

RECOMMENDATION. I recommend that the notice be signed and published.



Susan Alpert, Ph.D., M.D.

Attachments
Tab A - Notice
Tab B - Order
Tab C - S & E Summary

DECISION

Approved _____ Disapproved _____ Date _____

Prepared by Lynne A. Reamer, CDRH, HFZ-450 , [DATE PREPARED], 443-8320
Jan Donelson, CDRH, HFZ-450, [DATE PREPARED], 443-8320
Robert Mazzaferro, CDRH, HFZ-450, [DATE PREPARED], 443-8517

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food And Drug Administration

[DOCKET NO. _____]

Biotronik, Inc.; PREMARKET APPROVAL OF Dromos DR/DR-A and
Dromos SR/SR-B Cardiac Pacing Systems

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is
announcing its approval of the application by Biotronik,
Inc., Lake Oswego, OR, for premarket approval, under the
Federal Food, Drug, and Cosmetic Act (the act), of the
Dromos DR/DR-A and Dromos SR/SR-B Cardiac Pacing Systems.
FDA's Center for Devices and Radiological Health (CDRH)
notified the applicant, by letter of October 11, 1996, of
the approval of the application.

DATES: Petitions for administrative review by (insert date
30 days after date of publication in the FEDERAL REGISTER).

ADDRESSES: Written requests for copies of the summary of
safety and effectiveness data and petitions for
administrative review, to the Dockets Management Branch
(HFA-305), Food and Drug Administration, 12420 Parklawn Dr.,
rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Robert Mazzaferro,
Center for Devices and Radiological Health (HFZ-450),
Food and Drug Administration,
9200 Corporate Blvd.,
Rockville, MD 20850,
301-443-8517.

SUPPLEMENTARY INFORMATION: On February 21, 1996, Biotronik, Inc., Lake Oswego, OR 97035-5369, submitted to CDRH an application for premarket approval of the Dromos DR/DR-A and Dromos SR/SR-B Cardiac Pacing Systems. The BIOTRONIK Dromos DR and Dromos SR are rate adaptive multiprogrammable pulse generators. The Dromos DR is an atrial-based dual-chamber pacemaker and the Dromos SR is a single-chamber pacemaker suitable for either atrial or ventricular pacing therapy. The Dromos DR and Dromos SR have an accelerometer-based sensor and a rate-adaptive algorithm designed to automatically adjust the pacing rate to meet the patient's level of exertion. Rate adaptive pacing with the Dromos DR and Dromos SR pulse generators is indicated for patients exhibiting chronotropic incompetence and who would benefit from increased pacing rates concurrent with physical activity. Generally accepted indications for long-term cardiac pacing include, but are not limited to: sick sinus syndrome (i.e., bradycardia-tachycardia syndrome, sinus arrest, sinus bradycardia), sino-atrial (SA) block, second-



and third- degree AV block, and carotid sinus syndrome. Patients who demonstrate hemodynamic benefit through maintenance of AV synchrony should be considered for one of the dual-chamber or atrial pacing modes. Dual-chamber modes are specifically indicated for treatment of conduction disorders that require both restoration of rate and AV synchrony such as AV nodal disease, diminished cardiac output or congestive heart failure associated with conduction disturbances, and tachyarrhythmias that are suppressed by chronic pacing.

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Circulatory System Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

On October 11, 1996, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

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Opportunity for Administrative Review

Section 515(d)(3) of the act, (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the FEDERAL REGISTER. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before (insert date 30 days after date of publication in the FEDERAL REGISTER), file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information,





Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Joseph J. Schwoebel
Director, Clinical and Regulatory Affairs
Biotronik, Inc.
6024 Jean Road
Lake Oswego, Oregon 97035-5369

OCT 11 1996

Re: P950037
Dromos DR/DR-A and Dromos SR/SR-B Cardiac Pacing Systems
Filed: February 21, 1996
Amended: March 4, April 2, 15, 23, 26, May 3, August 19,
September 12, 13, 16, 20, and October 9, 1996

Dear Mr. Schwoebel:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Dromos DR/DR-A and Dromos SR/SR-B Cardiac Pacing Systems which consist of the following: Dromos DR Model #120851 and DR-A Model # 120907 Pulse Generators (dual chamber), Dromos SR Model # 120856 and SR-B Model # 120905 Pulse Generators (single chamber), PMS 1000 Programming and Monitoring System with Software Module SWM 1000, Version C06.C02.U. The PMS 1000 with SWM 1000, Version C01.C02.U was previously approved through P820076/S19 on January 24, 1996.

Rate adaptive pacing with the Dromos DR and Dromos SR pulse generators is indicated for patients exhibiting chronotropic incompetence and who would benefit from increased pacing rates concurrent with physical activity. Generally accepted indications for long-term cardiac pacing include, but are not limited to: sick sinus syndrome (i.e., bradycardia-tachycardia syndrome, sinus arrest, sinus bradycardia), sino-atrial (SA) block, second- and third- degree AV block, and carotid sinus syndrome. Patients who demonstrate hemodynamic benefit through maintenance of AV synchrony should be considered for one of the dual-chamber or atrial pacing modes. Dual-chamber modes are specifically indicated for treatment of conduction disorders that require both restoration of rate and AV synchrony such as AV nodal disease, diminished cardiac output or congestive heart failure associated with conduction disturbances, and tachyarrhythmias that are suppressed by chronic pacing.

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Page 2 - Mr. Joseph J. Schwoebel

We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval for Cardiac Pacemakers and Programmers" (enclosed). You may begin commercial distribution of the device upon receipt of this letter.

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that to ensure the safe and effective use of the device that the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii), insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

CDRH will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the act.

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

In addition under section 522(a) of the act, manufacturers of certain types of devices identified by the act or designated by FDA are required to conduct postmarket surveillance studies. FDA has identified under section 522(a)(1)(A) the above noted device as requiring postmarket surveillance.

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Upon approval and within thirty (30) days of first introduction or delivery for introduction of this device into interstate commerce you will be required to submit to FDA certification of the date of introduction into interstate commerce, a detailed protocol which describes the postmarket surveillance study, and a detailed profile of the study's principal investigator that clearly establishes the qualifications and experience of the individual to conduct the proposed study. For your information, general guidance on preparing a protocol for a postmarket surveillance study is enclosed. At that time you should submit five (5) copies to:

Postmarket Studies Document Center
1350 Piccard Drive (HFZ-544)
Rockville, Maryland 20850

Within sixty (60) days of receipt of your protocol, FDA will either approve or disapprove it and notify you of the Agency's action in writing. Do not undertake a postmarket surveillance study without an FDA approved protocol.

Failure to certify accurately the date of initial introduction of your device into interstate commerce, to submit timely an acceptable protocol, or to undertake and complete an FDA approved postmarket surveillance study consistent with the protocol, will be considered violations of section 522. In accordance with the Medical Device Amendments of 1992, failure of a manufacturer to meet its obligations under section 522 is a prohibited act under section 301(q)(1)(C) of the act (21 U.S.C. 331(q)(1)(C)). Further, under section 502(t)(3) of the act (21 U.S.C. 352(t)(3)), a device is misbranded if there is a failure or refusal to comply with any requirement under section 522 of the act. Violations of sections 301 or 502 may lead to regulatory actions including seizure of your product, injunction, prosecution, or civil money penalties or other FDA enforcement actions including (but not limited to) withdrawal of your PMA.

If you have questions concerning postmarket surveillance study requirements, contact the Postmarket Surveillance Studies Branch, at (301) 594-0639.

Under section 519(e) of the act (as amended by the Safe Medical Devices Act in 1990), manufacturers of certain devices must track their products to the final user or patient so that devices can be located quickly if serious problems are occurring with the products. The tracking requirements apply to (1) permanent implants the failure of which would be reasonably likely to have serious adverse health consequences; (2) life sustaining or life supporting devices that are used outside of device user facilities the failure of which would be

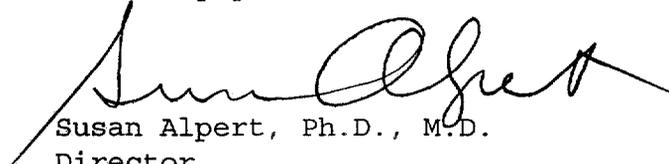
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reasonably likely to have serious adverse health consequences; and (3) other devices that FDA has designated as requiring tracking. Under section 519(e), FDA believes that your device is a device that is subject to tracking because it is a permanent implant whose failure would be reasonably likely to have serious adverse consequences.

FDA's tracking regulations, published in the FEDERAL REGISTER on August 16, 1993, appear at 21 CFR Part 821. These regulations set out what you must do to track a device. In addition, the regulations list example permanent implant and life sustaining or life supporting devices that FDA believes must be tracked at 21 CFR § 821.20(b) and the devices that FDA has designated for tracking at 21 CFR § 821.20(c). FDA's rationale for identifying these devices is set out in the FEDERAL REGISTER (57 FR 10705-10709 (March 27, 1991), 57 FR 22973-22975 (May 29, 1992), and 58 FR 43451-43455 (August 16, 1993)).

If you have questions concerning this approval order, please contact Robert Mazzaferro, P.E., RAC, at (301) 443-8517.

Sincerely yours,



Susan Alpert, Ph.D., M.D.

Director

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosures

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**CONDITIONS OF APPROVAL
FOR CARDIAC PACEMAKERS AND PROGRAMMERS**

APPROVED LABELING. As soon as possible, and before commercial distribution of your device, submit three copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Boulevard, Rockville, Maryland 20850.

ADVERTISEMENT. No advertisement or other descriptive printed material issued by the applicant or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations which require a PMA supplement cannot be briefly summarized, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the **addition** of, but **not the replacement** of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effected." This acknowledgment is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. **This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.**

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Boulevard, Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

- (1) Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

(2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

- (a) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and
- (b) reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each identified report when so notified by FDA.

In addition to the above and in order to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use, the annual postapproval reports shall include, separately for each model number (if applicable), the following information known by or reported to the applicant:

- (1) The number of pacemakers domestically implanted and the number of reported explants and deaths.
- (2) A breakdown of the reported deaths into pacemaker related and non-pacemaker related.
- (3) A breakdown of the reported explants into the numbers reported at end of battery life, having complications unresolvable by programming and for other reasons with safety and effectiveness issues which can be derived from the reports stated.
- (4) The number of pacemakers returned to the applicant for cause from domestic sources with a breakdown into the numbers currently in analysis, operating properly, at normal battery depletion and failed, with the failure mechanisms described.
- (5) A cumulative survival table for the pacemakers.
- (6) The number of programmers and modules shipped and the number of returns with a breakdown into the numbers currently in analysis, operating properly and failed, with the failure mechanisms described.

ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Boulevard, Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

- (1) A mixup of the device or its labeling with another article.
- (2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and
 - (a) has not been addressed by the device's labeling or
 - (b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.
- (3) Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION.

The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984, and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to FDA whenever they receive or otherwise became aware of information that reasonably suggests that one of its marketed devices

- (1) may have caused or contributed to a death or serious injury or
- (2) has malfunctioned and that the device or any other device marketed by the manufacturer or imported would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for this PMA, you shall submit the appropriate reports required by the MDR Regulation and identified with the PMA reference number to the following office:

Division of Surveillance Systems (HFZ-531)
Center for Devices and Radiological Health
Food and Drug Administration
1350 Piccard Drive, Room 340
Rockville, Maryland 20850
Telephone (301) 594-2735

Events included in periodic reports to the PMA that have also been reported under the MDR Regulation must be so identified in the periodic report to the PMA to prevent duplicative entry into FDA information systems.

Copies of the MDR Regulation and an FDA publication entitled, "An Overview of the Medical Device Reporting Regulation," are available by written request to the address below or by telephoning 1-800-638-2041.

Division of Small Manufacturers Assistance (HFZ-220)
Center for Devices and Radiological Health
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dromos DR/DR-A Dromos SR/SR-B Cardiac Pacing System

Summary of Safety and Effectiveness

BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035



Summary of Data and Information

I. GENERAL INFORMATION

Device Generic Name: Implantable Pacemaker Pulse Generator and Pacemaker Programming and Monitoring System

Device Trade Name: Dromos DR/DR-A/SR/SR-B Cardiac Pacing Systems, PMS 1000 Programming and Monitoring System, and SWM 1000 Software Module (version C07.C02.U)

Applicant's Name and Address: Biotronik, Inc.
6024 Jean Road
Lake Oswego, OR 97035-5369

Pre-Market Approval Application Number: P950037

Date of Notice of Approval to the Applicant: OCT 1 1996

II. INDICATIONS FOR USE

Rate adaptive pacing with the Dromos DR and Dromos SR pulse generators is indicated for patients exhibiting chronotropic incompetence and who would benefit from increased pacing rates concurrent with physical activity.

Generally accepted indications for long-term cardiac pacing include, but are not limited to: sick sinus syndrome (i.e., bradycardia-tachycardia syndrome, sinus arrest, sinus bradycardia), sino-atrial (SA) block, second- and third-degree AV block, and carotid sinus syndrome.

Patients who demonstrate hemodynamic benefit through maintenance of AV synchrony should be considered for one of the dual-chamber or atrial pacing modes. Dual-chamber modes are specifically indicated for treatment of conduction disorders that require both restoration of rate and AV synchrony such as AV nodal disease, diminished cardiac output or congestive heart failure associated with conduction disturbances, and tachyarrhythmias that are suppressed by chronic pacing.

III. DEVICE DESCRIPTION

The BIOTRONIK Dromos DR and Dromos SR are rate adaptive multiprogrammable pulse generators. The Dromos DR is an atrial-based dual-chamber pulse generator and the Dromos SR is a single-chamber pulse generator suitable for either atrial or ventricular pacing therapy. The Dromos DR and Dromos SR pulse generators have an accelerometer-based sensor and a rate-adaptive algorithm designed to automatically adjust the pacing rate to meet the patient's level of exertion.

The features of the Dromos DR pulse generator include programmable lower rate, hysteresis rate, upper tracking rate, dynamic AV delay, and the dual demand automatic mode conversion feature. The atrial and ventricular channels have independently programmable pulse amplitude, pulse width, sensitivity, refractory periods, pacing polarity, and sensing polarity. Additional programmable features include programmable atrial refractory extension, safety AV delay pacing, and ventricular blanking periods. The features of the Dromos SR include programmable lower rate, pulse amplitude, pulse width, sensitivity, refractory period, pacing polarity, and sensing polarity.

A piezoelectric sensor mounted on the hybrid circuit converts patient motion into an electrical signal. Integration of the sensor onto the hybrid circuit eliminates potential pulse generator response to external pressure. When programmed to a rate-adaptive mode, the sensor output signal is processed in order to obtain a signal proportional to the degree of motion sensed. The criteria used for signal processing include the intensity and frequency ranges characteristic of human physical activity. The sensor indicated rate automatically adjusts between the programmed lower rate and the maximum sensor rate in response to patient motion.

The rate-adaptive functions of the pulse generators include five independently programmable parameters: sensor gain, sensor threshold, rate increase, rate decrease, and maximum sensor rate. Adjustment of the sensor gain determines the amount of rate response for a given level of activity. Adjustment of the sensor threshold determines the minimum amount of activity required before the sensor response is activated. Adjustment of the rate increase and rate decrease parameters affects how quickly the sensor indicated pacing rate changes. The maximum sensor rate provides the upper limit of the sensor indicated pacing rate. Adjustment of each of these parameters allows the rate-adaptive characteristics of the pulse generator to be easily tailored for each individual patient.

The Dromos DR and Dromos SR pulse generators are available with two different connector types. The Dromos DR designates pulse generators with connectors compatible with IS-1 leads. The Dromos DR-A designates pulse generators with connectors compatible with 5 mm leads. The Dromos DR-A lead connector is intended for use with chronic five millimeter unipolar leads. Unless specifically indicated otherwise, all references to the Dromos DR apply to both the Dromos DR and the Dromos DR-A pulse generators. The Dromos SR designates pulse generators with

connectors compatible with IS-1 leads. The Dromos SR-B designates pulse generators with connectors compatible with five and six millimeter leads. The Dromos SR-B lead connector is intended for use with chronic five or six millimeter unipolar leads. Unless specifically indicated otherwise, all references to the Dromos SR apply to both the Dromos SR and the Dromos SR-B pulse generators.

The can of the Dromos DR and Dromos SR pulse generators is made of titanium, and the header is made of epoxy. The Dromos DR and Dromos SR headers are designed to be self-sealing and consist of setscrews accessed through self-sealing silicone plugs. The Dromos DR-A/SR-B headers utilize set screws and sealing caps.

Programming and interrogation of the Dromos DR and Dromos SR pulse generators are controlled through the use of the PMS 1000 Programming and Monitoring System and the SWM 1000 Software Module (version C07.C02.U). This software version allows programming and interrogation of the Dromos DR and Dromos SR pulse generators as well as BIOTRONIK market released pulse generators. The PMS 1000 Programming and Monitoring System allows access to a wide range of Dromos DR and Dromos SR diagnostic features including pacing threshold tests, battery and lead evaluation, simultaneous intracardiac electrograms (IEGMs) and real-time marker transmission, trend monitors, and event counters. Storage of patient data is also available, including implant date, last follow-up date, patient initials, symptom, etiology of clinical rhythm, ECG indication, and lead polarities. There is no software contained within the Dromos DR and Dromos SR pulse generators such as a ROM. All software is contained within the software module of the PMS 1000. The pulse generators respond to programming instructions by temporarily storing information in a shift-register which sets the operating features of the pulse generator.

IV. CONTRAINDICATIONS

Use of the Dromos pulse generators is contraindicated as follows:

- Unipolar pacing is contraindicated for patients with an implanted cardioverter-defibrillator (ICD) because it may cause unwanted delivery or inhibition of ICD therapy.
- Single-chamber atrial pacing is contraindicated for patients with impaired AV nodal conduction.
- Dual-chamber and single-chamber atrial pacing is contraindicated for patients with chronic refractory atrial tachyarrhythmias.

V. WARNINGS

- **Rate adaptive pacing** should be used with care in patients unable to tolerate increased pacing rates.

NOTE: The therapeutic and diagnostic procedures listed below may result in latent damage to the pulse generator. This damage may not be detected when testing pulse generator function after the procedure, but may become manifest at a later time, resulting in pulse generator malfunction or failure

- Use of **therapeutic diathermy** equipment is to be avoided for pulse generator patients.
- **Transcutaneous electrical nerve stimulation (TENS)** may interfere with pulse generator function. If necessary, the following measures may reduce the possibility of interference:
 - Place the TENS electrodes as close to each other as possible.
 - Place the TENS electrodes as far from the pulse generator/lead system as possible.
 - Monitor cardiac activity during TENS use
- **Magnetic resonance imaging** should be avoided as it has been shown to cause movement of the pulse generator within the subcutaneous pocket and may cause pain and injury to the patient and damage the pulse generator.

VI. PRECAUTIONS

Storage

- Recommended storage temperature range is 5° to 55°C (41°-131°F). Exposure to temperatures outside this range may result in pulse generator malfunction.
- Exposure to **low temperatures** (below 0°C) may cause a false elective replacement indication (ERI) to be present. If this occurs, warm the device to room temperature and reset the ERI with magnet application.

Pre-Implant

- **Do not drop.** If an unpackaged pulse generator is dropped onto a hard surface, return it to BIOTRONIK.
- If resterilization is necessary, **use only ethylene oxide** at temperatures not exceeding 55° C (131° F), and aerate the packaged device until the concentration of ethylene oxide residue is below the level prescribed by applicable federal and/or state laws. **Do not use** steam sterilization (flash) or

autoclave a pulse generator.

- **Do not resterilize** a pulse generator or package that becomes contaminated by contact with body fluids.
- Accessories packaged with the pulse generator are intended for one-time use. Do not resterilize them.

Lead Connection

- **Lead/pulse generator** compatibility should be confirmed with the pulse generator and/or lead manufacturer prior to the implantation of a pacing system.

The Dromos DR and SR pulse generators are designed for use with bipolar leads having a 3.2 mm connector. The Dromos DR-A is designed for use with unipolar leads having a 5 mm Pin-Lock® PE connector. The Dromos SR-B is designed for use with an unipolar lead having a 6 mm Pin-Lock® PEC connector.

- **Lead configuration** determines proper programming of the pulse generator. Pacing will not occur with a unipolar lead if the lead configuration is programmed to bipolar.
- Failure to back-off the setscrew(s) prior to insertion of lead connector(s) may result in damage to the lead(s), and/or difficulty connecting lead(s).
- Do not overtighten the setscrew.
- Failure to properly insert the torque wrench into the perforation at an angle perpendicular to the connector receptacle may result in damage to the plug and its self-sealing properties. (DR/SR Models)
- If setscrews are not sealed with the provided sealing cap(s), pulse generator malfunction may occur. (DR-A, SR-B Models)

Electromagnetic Interference (EMI)

Patients should exercise reasonable caution in avoidance of devices which generate a strong electric or magnetic field. If EMI inhibits operation of a pulse generator or causes it to revert to asynchronous operation at the programmed pacing rate or at the magnet rate, moving away from the source or turning it off will allow the pulse generator to return to its normal mode of operation.

Some potential EMI sources include:

Hospital and Medical Environments

- **Electrosurgical cautery** could induce ventricular arrhythmias and/or fibrillation, or may cause asynchronous or inhibited pulse generator operation. If use of electrocautery is necessary, the current path (ground plate) should be kept as far away from the pulse generator and leads as possible.
- **Lithotripsy** may damage the pulse generator. If lithotripsy must be used, do not focus the beam near the pulse generator.
- **External defibrillation** may damage the pulse generator. Attempt to minimize current flowing through the pulse generator and lead system by following these precautions:
 - Position defibrillation paddles as far from the pulse generator as possible. Attempt to minimize current flowing through the pulse generator and leads by positioning the defibrillation paddles perpendicular to the implanted pulse generator/lead system.
 - Use the lowest energy output (watt seconds) as clinically acceptable.
 - Confirm pulse generator function following any internal or external defibrillation.
- **High radiation sources** such as cobalt 60 or gamma radiation should not be directed at the pulse generator. If a patient requires radiation therapy in the vicinity of the pulse generator, place lead shielding over the device to prevent radiation damage.

Home Occupational Environments

- **High voltage power transmission lines** may generate enough EMI to interfere with pulse generator operation if approached too closely.
- **Communication equipment** such as microwave transmitters, linear power amplifiers, or high-power amateur transmitters may generate enough EMI to interfere with pulse generator operation if approached too closely.
- **Commercial electrical equipment** such as arc welders, induction furnaces, or resistance welders may generate enough EMI to interfere with pulse generator operation if approached too closely.
- Electric hand-tools and electric razors (used directly over the skin of the pulse generator) have been reported to cause pulse generator disturbances. **Home appliances** which are in good working order and properly grounded do not usually produce enough EMI to interfere with pulse generator operation.

Cellular Phones

Recent studies have indicated there may be a potential interaction between cellular phones and pulse generator operation. Potential effects may be due to either the radio frequency signal or the magnet within the phone and could include inhibition or asynchronous pacing when the phone is within close proximity (within 6 inches or 15 centimeters) to the pulse generator.

Based on testing to date, effects resulting from an interaction between cellular phones and the implanted pulse generators have been temporary. Simply moving the phone away from the implanted device will return it to its previous state of operation. Because of the great variety of cellular phones and the wide variance in patient physiology, an absolute recommendation to cover all patients cannot be made. Patients having an implanted pulse generator who operate a cellular phone should:

- Maintain a minimum separation of 6 inches (15 centimeters) between a hand-held personal cellular phone and the implanted device. Portable and mobile cellular phones generally transmit at higher power levels compared to hand held models. For phones transmitting above 3 watts, maintain a minimum separation of 12 inches (30 centimeters) between the antenna and the implanted device.
- Patients should hold the phone to the ear opposite the side of the implanted device. Patients should not carry the phone in a breast pocket or on a belt within 6 inches (15 centimeters) of the implanted device as some phones emit signals when they are turned ON but not in use (i.e., in the listen or standby mode). Store the phone in a location opposite the side of implant.

Disposal

Never incinerate a pulse generator. Be sure the pulse generator is explanted before a patient who has died is cremated.

Programming

- Use only appropriate BIOTRONIK programmers equipped with appropriate software to program the Dromos pulse generators. Do not use programmers of other manufacturers.
- Computerized systems are subject to EMI or "noise". In the presence of such interference, telemetry communication is interrupted and prevents improper programming
- Extreme programming changes should only be made after careful clinical assessment. Clinical judgement should be used when programming permanent pacing rates below 40 ppm or above 100 ppm

- Use of the OFF mode should be avoided in pulse generator dependent patients. The OFF mode can be transmitted as a temporary program only to permit evaluation of the patient's spontaneous rhythm

VII. ALTERNATIVE PRACTICES AND PROCEDURES

Cardiac pacing is the standard treatment for the indications described above. In certain instances, surgery and/or drug therapy may provide alternatives to cardiac pacing. Other commercially available pulse generators may provide alternatives to the pulse generators described above.

VIII. MARKETING HISTORY

The Dromos DR and Dromos SR pulse generators and the associated software for these devices have not been marketed in the United States by BIOTRONIK or by any other entity. The PMS 1000 System was approved for market release on January 24, 1996, (P820076/S19) for use with all market released BIOTRONIK pulse generators.

The Dromos DR and Dromos SR pulse generators received the CE Mark in September, 1994 under Council Directive 90/385/EEC of the Commission of the European Communities. As of July 1996, more than 8,400 Dromos DR and Dromos SR pulse generators have been implanted outside the United States. The PMS 1000 programmer was CE marked by EC Type-Examination under Council Directive 90/385/EEC of the Commission of the European Communities in September, 1994. As of July, 1996, more than 1,650 PMS 1000 programmers have been in clinical use outside the United States.

IX. ADVERSE EVENTS

Observed Adverse Events

The Dromos DR Clinical Study involved 273 patients with a cumulative implant duration of 1418 months (mean implant duration 5.2 months). Nine Dromos DR patients died during the course of the study; none of the deaths were judged to be device-related. One Dromos DR pulse generator was explanted during the study, secondary to infection.

Table 1 reports the adverse events (AEs) on a per patient basis.

Table 1. Adverse Events Reported in More Than One Patient
All Dromos DR patients (N=273)

	# pts (n=273)	% of patients	# of AEs
Observations ¹ (Total)	79*	29%	86
Arrhythmias	34	12.5%	36
Pulse generator Mediated Tachycardia	11	4.0%	12
Atrial Loss of Sensing	10	3.7%	10
Atrial Loss of Capture	8	2.9%	8
Premature AV Stimulation	4	1.5%	4
Muscle/diaphragmatic Stimulation	3	1.1%	3
Unexplained Syncope	3	1.1%	3
Complications ² (Total)	14*	5.1%	14
Atrial Lead Dislodgement	6	2.2%	6
Ventricular Lead Dislodgement	4	1.5%	4

¹ Observations are adverse events which are correctable by noninvasive measures, e.g., reprogramming.

² Complications are adverse events requiring invasive measures to correct, e.g., surgical intervention.

* Total exceeds reported events due to 6 observations and 4 complications each having only one occurrence.

The Dromos SR Clinical Study involved 91 patients with a cumulative implant duration of 327 months (mean implant duration 3.6 months). Three patients died during the course of the study; none of the deaths were judged to be device-related. During this clinical study, there were 3 ventricular lead dislodgements requiring invasive lead repositioning. There were two observations having only one occurrence each.

Potential Adverse Events

In addition to the adverse events reported in the clinical study, other possible adverse events may occur with this type of device based on implant experience including:

- Cardiac tamponade
- Cardiac perforation
- Air embolism
- Pocket erosion
- Infection
- Lead fracture/insulation damage

- Lead dislodgment
- Lead-related thrombosis
- Body rejection phenomena
- Muscle or nerve stimulation
- Elevated pacing thresholds
- Pocket hematoma
- Myopotential sensing
- Local tissue reaction/fibrotic tissue formation
- Pulse generator migration
- Pulse generator-mediated tachycardia (dual-chamber modes only)
- Undersensing of intrinsic signals

X. SUMMARY OF STUDIES

A. Nonclinical Laboratory Studies

The nonclinical laboratory (bench) testing provides information relevant to the Dromos DR and Dromos SR pulse generator, PMS 1000 programmer and SWM 1000 C07.C02.U programmer software. The design requirements and specifications were deemed appropriate for these devices.

1. Device Tests

a. Component Testing

Components in the Dromos DR and Dromos SR system previously used in other BIOTRONIK designs were qualified for use and the test documentation was provided in previously approved product submissions. These components include such items as the feedthrough and header (Pikos LP 01, Pikos E 01-B, Gemnos TC 04 pulse generators), housing and battery (Pikos LP 01 and Gemnos TC 04 pulse generators).

Twenty-two hybrid circuits used in the Dromos DR and Dromos SR were subjected to temperature cycling, constant acceleration, accelerated life tests, ventricular and atrial sensitivity, atrial and ventricular pulse amplitude, load and demand current, telemetry accuracy, ECG filter response, and end of service (EOS) trip voltage. Die shear/bond strength and mechanical shock/vibration tests were performed on five hybrid circuits. All of the hybrid circuit tests were performed on Dromos DR circuits (860-00) in as much as the components are identical. The hybrids were qualified for use in implantable pulse generators by successful completion of the above mentioned tests.

b. Finished Device Testing

Electrical design verification tests evaluate rate-adaptive functions, programming behavior, pulse generator functions, hybrid circuit component tests and safety tests

(including electromagnetic interference). Dromos DR and Dromos SR pulse generators were evaluated with electrical, mechanical and electromagnetic interference testing. All test results demonstrated conformance to the device design specifications.

The electrical design verification tests consisted of an assessment of programming and functionality characteristics of multiple pulse generators during normal operation and exposed to various external conditions (e.g., EMI, High Frequency Surgery (e.g., electrocautery), Electrostatic Discharge, external defibrillation).

A series of mechanical tests were performed on multiple complete pulse generators or case assemblies. These tests consist of evaluations of the self-sealing header, including lead insertion/extraction, shock and vibration testing, temperature cycle testing, helium leakage testing, long-term effect of saline and transportation testing. All test results conformed to device specifications

BIOTRONIK has followed the requirements of various international test standards, including: ISO 5841-3, EN 50061, VDE 0750, DIN 40046, MIL-STD-883 and numerous proprietary test requirements

2. Biocompatibility

Biocompatibility test data of the tissue/blood contacting materials used for the Dromos DR and Dromos SR pulse generators are also used in currently marketed BIOTRONIK pulse generators and their biocompatibility has been established in previously approved PMA applications (P820076/S14, S16) and a 510(k) premarket notification (K953044).

Programmer/Software Testing

The PMS 1000 Programmer and SWM C07.C02.U Software Module have been tested extensively in the laboratory. Hardware tests to demonstrate the overall electrical and mechanical safety of the PMS 1000 were conducted on multiple devices in accordance with numerous international standards, including IEC 601, DIN VDE 0750, EN 60601, and AAMI Standards ES1-058 and EC-11. All electrical and mechanical safety requirements were met. FDA previously reviewed and approved the PMS 1000 safety and effectiveness testing in a separate PMA supplement (P820076/S19).

In addition, BIOTRONIK tested the software according to its internal procedures. The software test protocol follows the FDA Reviewer Guidance document on computer controlled medical devices undergoing 510(k) review. This document makes provisions for a description of the software development process, design and interface specifications test and evaluation process, safety concept and hazard analysis, verification and validation testing.

The PMS 1000 and SWM 1000 C07.C02.U passed all hardware and software testing for their intended use as components of the Dromos DR and Dromos SR Cardiac Pacing Systems.

B. Clinical Studies

A clinical study was conducted to evaluate the safety and effectiveness of the Dromos DR and Dromos SR pacing systems. This study was initiated on November 3, 1994 under IDE G940050. Unlike the clinical protocol for the Dromos DR, the protocol for the Dromos SR was divided into two portions. The first portion of the study, referred to as the "focused" portion of the study, included over twenty patients that completed exercise testing, daily activity testing, and a twenty-four hour Holter recording. Additionally, these "focused" patients were seen for an additional follow-up at three months post-implant. The patients enrolled in the "routine" portion of the study underwent procedures consistent with standard pulse generator follow-ups.

1. Objectives of the Study

Dromos DR

The primary objective of this clinical study was to evaluate the safety and effectiveness of the Dromos DR pulse generator and the utility of the DDDR pacing mode in patients with chronotropic incompetence (CI) in a crossover, double-blind study. CI was defined as the ability to achieve a heart rate of a) 60% of their age predicted maximum (220 - age), or b) 100 bpm. Clinical data at implantation and at subsequent follow-up evaluations were collected and analyzed. The assessment of safety for this device was based on the collection, analysis, and reporting of all adverse events. Specific safety and effectiveness aspects of the Dromos DR pacing system which were analyzed included:

- analysis of exercise testing in the DDDR mode completed at the six-week follow-up interval to determine the appropriateness of the rate increase during the initial stages of exercise and the appropriateness of the rate decrease following the cessation of exercise,
- analysis of twenty-four hour Holter recordings taken at the one-month follow-up visit to determine the incidence and severity of pacing and sensing abnormalities and the stability of pacing rates during periods of rest and sleep,
- investigator's assessment of patient/pulse generator interaction during required follow-up evaluations. This includes patient experiences, review of ECG tracings, current programmed settings, and clinical assessments taken at implant and subsequent follow-up evaluations to assess appropriate pacing function,
- interaction between the programmer, PMS 1000, with SWM 1000 (version C02.C02.U) and the Dromos DR including interrogation, programming, magnet operation, and diagnostic functions, and
- chronic performance of the implanted pulse generator

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For those patients characterized as CI, oxygen consumption, exercise duration, and heart rate data were collected at the six-week follow-up during paired exercise tests using the Chronotropic Assessment Exercise Protocol (CAEP). This protocol was used because of its specific relevance to this study population. BIOTRONIK quantified the results of the exercise tests in terms of:

- maximum oxygen consumption,
- oxygen consumption at anaerobic threshold,
- total exercise duration,
- exercise time at anaerobic threshold, and
- heart rate at anaerobic threshold.

Table 2 provides the protocol requirements for each follow-up for the Dromos DR study.

Table 2: Dromos DR Follow-Up Requirements

Required Procedure	Pre-Release	One Month	Six Weeks	Three Months	Six Months	Twelve Months	Eighteen Months
ECG Demand/Magnet	X	X	X*	X*	X	X	X
Parameter Interrogation	X	X	X*	X*	X	X	X
Exercise Treadmill (CAEP)		X*					
Twenty-Four Hour Holter Monitor		X*					
Metabolic Exercise Treadmill			X*				

An "*" in this table refers to testing that is required only during the Phase I and early Phase II portion of the study.

Dromos SR

The primary objective of this portion of the clinical study was to examine the safety and effectiveness of the Dromos SR as a single chamber, rate-adaptive pulse generator. Clinical data at implantation and at subsequent follow-up evaluations were collected and analyzed. Table 3 provides the protocol requirements for each follow-up for the Dromos SR study.

The assessment of the safety of this device was based upon the collection, analysis, and reporting of all adverse events. Specific safety and effectiveness aspects of the Dromos SR pacing system that were analyzed include:

- chronic performance of the implanted pulse generator based on the reporting of all adverse events,
- interaction between the programmer, PMS 1000, with SWM 1000 version C03.C02.U and the Dromos SR including interrogation, programming, magnet

- operation, and diagnostic functions,
- investigator's assessment of patient/pulse generator interaction during required follow-up evaluations including patient experiences, review of ECG tracings, current programmed settings, and clinical assessments taken at implant and subsequent follow-up evaluations to assess appropriate pacing function, and
- analysis of twenty-four hour Holter recordings and daily activity tests at the one-month follow-up for stability of pacing rates during periods of rest and sleep and the incidence and severity of pacing and sensing abnormalities.

The effectiveness of the single-chamber rate-adaptive mode of the Dromos SR was assessed through two physician-monitored activity tests, including analysis of:

- Holter recordings during daily activity testing, including periods of rest, slow and fast walking, stair climbing, and arm movements at the one-month follow-up for appropriateness of rate response during varying activity levels, and
- continuous ECG recordings during a CAEP exercise test in the rate-adaptive mode quantified in terms of total exercise duration, maximum achieved heart rate, and total metabolic equivalent units (METs) achieved. In standard physiological terms, 1 MET is defined as the amount of O₂ consumed at rest.

Table 3: Dromos SR Follow-Up Requirements

Required Procedure	Pre-Release	One-Month	Three-Months*	Six-Months	Twelve-Months
ECG Demand/Magnet	X	X	X*	X	X
Parameter Interrogation	X	X	X*	X	X
Exercise Treadmill (CAEP)		X*			
Twenty-Four Hour Holter Recording with a Daily Activity Test		X*			

An "*" in this table refers to testing that is required only during the "focused" portion of the study.

Summary

The objectives of the clinical study were similar for the Dromos DR and SR pulse generators. Safety and effectiveness endpoints and testing requirements were essentially identical, allowing pooling of these two studies into one database for evaluation. The major difference between these two clinical studies focused on clinical benefit of the rate-adaptive mode. The Dromos DR clinical study was designed to prove clinical benefit, the Dromos SR clinical study was designed to demonstrate appropriateness of the rate-adaptive mode.

2. Results of the Clinical Study

a. Patient Population

Dromos DR

The indications for inclusion into this clinical study follow those recommended in the Class I definitions in the ACC/AHA Task Force Report¹. The primary indication for this clinical study was the DDDR mode. Patients were selected from those in whom dual-chamber pacing was indicated, and specifically, chronotropically compromised individuals, where increased pacing rates in response to exercise would be expected in the rate-adaptive mode. These indications included but were not limited to sick sinus syndrome and AV block.

Dromos SR

The indications for the Dromos SR pulse generator follow those recommended in the Class I definitions in the ACC/AHA Task Force Report. The primary indication for this clinical study was the SSIR mode. The SSIR mode designates that the Dromos SR pulse generator is indicated for implantation as a single-chamber ventricular (VVIR) or single-chambered atrial (AAIR) rate-adaptive pulse generator.

- The indications for the VVIR/VVI modes include any symptomatic bradyarrhythmia where there is no significant atrial contribution. Examples would be, but are not limited to, ventricular bradyarrhythmia, atrial fibrillation, or atrial flutter.
- The indications for the AAIR/AAI modes include any symptomatic sinus node dysfunction where there is adequate AV conduction noted.

A total of 364 patients were enrolled in this study as of July 31, 1996; 91 have undergone initial implantation of the Dromos SR, 273 have undergone implantation of Dromos DR. The Dromos SR group had a total implant duration of 326.8 months with a mean implant duration of 3.6 ± 0.3 months. There have been 46 (51%) Dromos SR patients implanted for greater than ninety days. The Dromos DR group had a total implant duration of 1418.4 months with a mean implant duration of 5.2 ± 0.2 months. There have been 172 (63%) Dromos DR patients implanted for greater than ninety days.

The mean age of the Dromos DR study population is 71 years with a range of 31 - 95 years. There are 145 males and 128 females enrolled. Based on the clinical data gathered, the "average" patient in this study would be a 71 year old male with symptoms of bradycardia, dizziness, and syncope. His etiology would be conduction system fibrosis leading to sick sinus syndrome with bradycardia and some degree of heart block.

¹ Guidelines for Implantation of Cardiac Pacemakers and Antiarrhythmic Devices. JACC, Vol. 18, No. 1, July 1991; 1-13.

The mean age of the Dromos SR study population is 75 years with a range of 48 - 99 years. There are 55 males and 36 females enrolled. Based on the clinical data gathered, the "average" patient in this study is a 75 year old male with symptoms of bradycardia and dizziness. His etiology would be conduction system fibrosis leading to atrial fibrillation with slow ventricular response

Gender Bias Analysis

The results of the paired exercise testing were analyzed in order to determine if there were any statistically significant differences between males and females. There were 15 males and 6 females who completed paired exercise testing and reached anaerobic threshold (AT). Table 4 provides the results of these analyses. There were no statistically significant differences between males and females for any of the endpoints.

Table 4: Gender Analyses

Endpoint - Variable	Improvement in Variable (mean \pm SE)			Results
	All patients	Males	Females	
1 - Maximum O ₂ Consumption (mL/kg/minute)	2.61 \pm 0.60	2.91 \pm 0.82	2.07 \pm 0.56	F test for variances p = 0.04 t-test for unequal variances p=0.40
2 - O ₂ Consumption @ AT (mL/kg/minute)	1.50 \pm 0.59	0.80 \pm 0.61	3.26 \pm 1.20	F test for variances p=0.23 t-test for equal variances p=0.06
3 - Total Exercise Duration (minutes)	0.91 \pm 0.24	0.84 \pm 0.21	1.14 \pm 0.67	F test for variances p=0.02 t-test for unequal variances p=0.68
4 - Exercise Time @ AT (minutes)	0.69 \pm 0.31	0.31 \pm 0.35	1.61 \pm 0.52	F test for variances p=0.49 t-test for equal variances p=0.06
5 - Heart Rate @ AT (bpm)	29.48 \pm 4.00	30.13 \pm 4.77	27.83 \pm 8.01	F test for variances p=0.39 t-test for equal variances p=0.80

b. Exercise Results

Dromos DR

Table 5 presents the distribution of the patient's chronotropic status based on the results of the one-month CI screening treadmill grouped by the implanted device. Three patients were unable to complete the one-month DDD exercise test because of medical conditions such as atrial fibrillation (2) and high ventricular pacing thresholds (1).

Table 5: Chronotropic Status

Classification	Dromos DR
Total Patients Evaluated	28
Classified as CI	10(36%)
less than 60% of age predicted maximum	5
less than 100 bpm	10
met both criteria	5
Classified as CC	18(64%)
Total Patients Not Evaluated	3

Of the 28 Dromos DR patients completing this DDD exercise test, 10 (36%) of the patients were classified as chronotropically incompetent. The one-month exercise test was discontinued by the sponsor on October 17, 1995 based on reaching the number of chronotropically incompetent patients required in the sample size estimation.

Dromos SR

The Dromos SR patients enrolled into the "focused" portion were required to perform an exercise test in the rate-adaptive pacing mode. The purpose of this exercise test was to determine the appropriateness of the single-chamber rate-adaptive pacing function of the Dromos SR. Twenty patients completed the required exercise testing. A summary of the results of the exercise tests is presented in Table 6

Table 6: Exercise Test Summary

Result	Number
100% intrinsic rhythm due to atrial fibrillation with appropriate inhibition of sensor-driven pacing	6
100% sensor-driven pacing at or near the maximum sensor rate	7
A combination of intrinsic and sensor-driven pacing	7
Total	20

Overall, the exercise tests demonstrated appropriate sensor behavior of the Dromos SR pulse generator. Only two patients had the sensor gain adjusted following the exercise testing to further optimize their rate-adaptive parameters.

Table 7 provides the mean results obtained during the exercise testing.

Table 7: One-Month Exercise Test Results

Characteristic	Results
Number of Patients	20
Maximum Heart Rate Achieved (bpm) Mean \pm SE [95% CI]	128 \pm 22 [119, 138]
Total Exercise Time (minutes) Mean \pm SE [95% CI]	6.2 \pm 3.2 [4.8, 7.6]
Total METs (associated with CAEP) Mean \pm SE [95% CI]	4.2 \pm 1.9 [3.4, 5.0]

c. Twenty-Four Hour Holter Recording

Dromos DR

The primary purpose of the twenty-four hour Holter recording was to determine the incidence and severity of any pacing and sensing abnormalities. In addition, the recording was also used to determine the stability of pacing rates during periods of rest and sleep. All Phase I Dromos DR patients completed the Holter recording in a rate-adaptive mode. Specific instructions were given to each patient to keep a detailed diary during the duration of the recording. The investigator was asked to interpret the recording and the diary and to summarize the results. There were 22 Dromos DR twenty-four hour Holter recordings completed in this study. Of these recordings, 10 (45%) of the Dromos DR recordings noted sensing or pacing abnormalities. Most of these sensing and pacing abnormalities were not related to the implanted pulse generator but attributable to pulse generator programming, patient condition, lead position, or other reasons. Table 8 provides the specifics of the results. Note that numbers and percentages cannot be summed as there may have been more than one event noted on each recording.

Table 8: Twenty-Four Hour Holter Recordings

Result	Dromos DR
Normal Pacing and Sensing Pulse generator Behavior	12(55%)
Reported Events	13
Atrial Competition	2(9%)
Atrial Loss of Capture (Intermittent and Total)	1(5%)
Atrial Oversensing (Possible and Intermittent)	1(5%)
Atrial Undersensing (Intermittent and Possible)	2(9%)
Myopotential Inhibition	1(5%)
Pulse generator Mediated Tachycardia (Possible)	2(9%)
Premature AV Stimulation	4(18%)
Total Number of Holters Performed	22 (100%)

The Holter recordings demonstrated that there was a significant percentage of pacing and sensing abnormalities present during the required testing. However, normal Holter interpretations for the Dromos DR remained in the majority (55%). The majority of pacing and sensing abnormalities occurred as isolated instances and without any denoted patient symptoms or clinical sequelae. Some of the Holter observations, i.e., atrial loss of capture and atrial undersensing, were present during the follow-up evaluation prior to the Holter recording. Twenty-four hour Holter monitoring is a routine aspect of post-operative management of pulse generator therapy. The Dromos DR pulse generator has programmable values and features that were used to resolve most of the Holter recording findings.

The sensor behavior during the twenty-four hour Holter recording demonstrated an increase in pacing rate in response to the patient's daily activities such as walking, housework, or other activities. The sensor-driven pacing rate also demonstrated a decrease after cessation of the activity. There were no (0%) Dromos DR patients with reports of an aggressive rate-adaptive response to activity level. Generally, the pacing rate during rest and sleep periods was stable.

There were four (18%) Dromos DR patients with a small number of isolated occurrences of premature AV stimulation lasting for one pacing cycle. Under certain conditions and in singular cases, a shortened pacing interval corresponding to the upper tracking rate was observed following an atrial-based ventricular cycle close to the basic rate. There were no patient symptoms reported or negative clinical consequences of these isolated premature AV stimulations.

Dromos SR

The primary purpose of the twenty-four hour Holter recording was to determine the incidence and severity of any pacing and sensing abnormalities. In addition, the recording was also used to determine the stability of pacing rates during periods of rest and sleep. Analyses of the Holter recordings obtained during the daily activity test demonstrated the appropriateness of rate response during varying activity levels. Specific instructions were given to each patient to keep a detailed diary for the duration of the recording. The investigator was asked to interpret the recording and the diary and to summarize the results. In this study, there were 21 Dromos SR twenty-four hour Holter recordings completed on 21 patients. Of these, 19 (90.5%) of the Holter recordings demonstrated normal pacing and sensing behavior, and 2 (9.5%) showed rare instances of ventricular undersensing. This ventricular undersensing is not indicative of any malfunction of the Dromos SR. It is attributable to the programmed sensitivity setting, patient condition, lead position, or other reasons. There were no instances of sensor-driven pacing associated with diary entries noting sleep periods. Table 9 provides the specifics of the results.

Table 9: Dromos SR Twenty-Four Hour Holter Recordings

Characteristic	Number (Percentage)
Normal Pacing and Sensing Pulse generator Behavior	19 (90.5%)
Rare Ventricular Undersensing	2 (9.5%)
Total	21 (100%)

d. Daily Activity Test***Dromos SR***

There were 22 Dromos SR daily activity tests completed in this study. The test consisted of periods of rest, slow and fast walking, stair climbing and arm movements. Of the daily activity tests completed, 19 (86.4%) demonstrated appropriate sensor-driven pacing correlating with changing activity levels, and 3 (13.6%) showed some sensor-driven pacing during rest periods or standing. However, Holter timing errors may have complicated the analysis. The remainder of the twenty-four hour Holter recordings on these patients demonstrated normal pacing and sensing behavior according to the ECG recordings. Table 10 provides a summary of the 22 daily activity tests completed.

Table 10: Daily Activity Test Results

Result	Number (Percentage)
Sensor-driven pacing correlates with changing activities	19 (86.4%)
Some sensor-driven pacing noted during standing	2 (9.1%)
Some sensor-driven pacing noted during rest periods	1 (4.5%)
Total	22 (100%)

3. Clinical Benefit Endpoints***Dromos DR***

Exercise testing was required at the six-week follow-up for all patients classified as chronotropically incompetent at the one-month follow-up. Paired exercise tests were completed in the DDDR and DDD pacing modes in which oxygen consumption was measured and continuous ECG recordings were taken for the entire duration of a CAEP treadmill. The order of the tests was randomized, and the tests were completed on consecutive days at approximately the same time of day. In addition, both the patient and the person designated as the one to motivate the patient to exercise were blinded to the programmed mode of the device.

There were 25 patients who completed the six-week follow-up. One patient was unable

to complete the six-week paired exercise testing due to an intolerance of the mouth piece required during metabolic testing. Three additional patients were excluded from the analysis because they did not reach anaerobic threshold. Table 11 provides the results of the exercise tests for the 21 patients that completed the test and reached anaerobic threshold for both tests. This table includes data from both the Dromos DR and an earlier version of the Dromos DR implanted during the Phase I portion of the clinical study.

Table 11: Dromos DR Metabolic Exercise Testing at 6 Weeks

All chronotropically incompetent patients tested, n=21
Mean \pm SD and [95% confidence interval] *

Endpoints	DDDR Mode	DDD Mode	Difference [CI]
Maximum VO ₂ (mL/kg/minute)	20.4 \pm 8.0	17.8 \pm 6.2	2.67** \pm 2.77 [1.5, 3.8]
VO ₂ @ AT (mL/kg/minute)	14.6 \pm 3.6	13.1 \pm 4.0	1.5** \pm 2.71 [0.33, 2.6]
Total exercise time (minutes)	9.2 \pm 3.0	8.2 \pm 3.3	0.92** \pm 1.08 [0.45, 1.4]
Exercise time to AT (minutes)	6.3 \pm 2.4	5.7 \pm 2.8	0.69** \pm 1.43 [0.04, 1.3]
Heart rate @ AT (bpm)	113 \pm 16	84 \pm 16.5	29** \pm 18 [21, 37]

* 95% confidence interval = mean difference \pm 1.96 SEM

** Difference statistically significant, $p < 0.05$ by paired t-test

4. Observed Adverse Events

Dromos DR

There were a total of 93 adverse events reported during the study from November 3, 1994 to July 31, 1996. (See Table 1.) There is no prospective study with published data for the exact same pulse generator type and indications as the Dromos DR population to serve as a comparison for the incidence of adverse events. However, a retrospective study detailed the incidence of reported events in 486 patients between 1981 and 1988². The study did not look at simple pulse generator parameter reprogramming, only at mode reprogramming out of the DDD mode and invasive interventions to reposition dislodged leads. The patients followed had similar mean ages (71.4 years compared to 71 years) and gender (57% male compared to 53% male). Table 12 lists the adverse events requiring mode change for the retrospective study and the Dromos DR study population. Only Dromos DR adverse events that required mode conversion from the DDD or DDDR mode were used in this comparison. Based on this analysis of each type of adverse event, the rate of occurrence for the Dromos DR patients was statistically less than or equivalent to the "reported norms" for a similar study population (Fisher's exact test).

²Gross, J., et al. DDD Pacing Mode Survival in Patients with a Dual-Chamber Pacemaker. JACC 1992; 19:1536-1541.

5/1

Table 12: Comparison of Published Standards

Adverse Event Category	Retrospective group	Dromos DR	Test Statistic
Arrhythmias	48 (10%)	19 (7%)	0.11
Loss of atrial sensing	26 (5%)	1 (0.4%)	<0.0001
Lead dislodgement	11 (2%)	8 (2.9%)	0.79
Loss of atrial capture	5 (1%)	2 (0.7%)	0.51
Pulse generator mediated tachycardia	5 (1%)	1 (0.4%)	0.30
Diaphragmatic stimulation	5 (1%)	1 (0.4%)	0.51
Pulse generator failure	4 (1%)	0(0%)	0.17
Device malfunction	1 (1%)	0 (0%)	0.64
Loss of ventricular capture	0 (0%)	1 (0.4%)	1.00
Miscellaneous	5 (1%)	3 (1%)	0.69
Total	110 (110/486, 23%)	36 (36/273, 13.2%)	N/A

Dromos SR

There were a total of 5 observed adverse events reported during the study. Three were ventricular lead dislodgements requiring invasive lead repositioning. There were two observations having only one occurrence each.

There is no prospective study with published data for an identical pulse generator type and indications as the Dromos SR population to serve as a comparison for the incidence of adverse events. However, a prospective study detailed the incidence of complications in 258 patients between 1986 and 1988³. This study collected data related to invasive interventions to reposition dislodged leads and urgent reprogramming required outside of routine follow-up because of symptomatic reasons such as undersensing, oversensing, failure to capture, or muscle stimulation. The patients followed had similar mean ages (75 years compared to 76 years in the Dromos SR study) and gender (57% male compared to 60% male in the Dromos SR study, Chi-squared, p=0.12). Table 13 lists the adverse events requiring reprogramming and lead interventions for the historical control study and the Dromos SR study population. Based on this analysis, the rates of adverse events for the Dromos SR patients were similar to “reported norms” for a similar study population (all comparisons using Fisher’s exact test, non-significant differences).

³ Mueller, X. Et al. Complications after Single versus Dual Chamber Pacemaker Implantation. PACE, June 1990; 711-713

Table 13: Comparison of Published Results

Event Category	Historical Control	Dromos SR	p-value
Complications requiring an urgent reprogramming:			
Loss of sensing	10 (3.9%)	0 (0%)	0.12
Loss of capture	6 (2.3%)	3 (3%)	0.82
Muscle stimulation	7 (2.7%)	1 (1%)	0.34
Sensor related issues	0 (0%)	1 (1%)	1.00
Total	23 (8.9%)	5 (5%)	—
Complications requiring lead repositioning or revision:			
Lead dislodgment	3 (1.2%)	3 (3%)	0.96
Infection	2 (0.8%)	0 (0%)	0.55
Lead Revision 2° to sensing problem	2 (0.8%)	0 (0%)	0.55
Lead Revision 2° to muscle stimulation	2 (0.8%)	0 (0%)	0.55
Lead Revision 2° to pulse generator syndrome	1 (0.4%)	0 (0%)	0.74
Lead Revision 2° to miscellaneous	3 (1.2%)	0 (0%)	0.40
Total	13 (5%)	3 (3%)	—

5. Patient Complaints

Dromos DR

During the Dromos DR clinical study there were two (0.2%) patient complaints out of 1048 follow-up visits. One complaint involved the patient feeling palpitations during periods of low activity. The sensor gain was subsequently reprogrammed to a lower level and retested during a daily activity test. The daily activity test demonstrated appropriate rate response to changes in activity levels. There were no further complaints from this patient after the reprogramming. One complaint resulted from pain at the generator implant site and was resolved by repositioning the generator pocket medially.

Dromos SR

During the Dromos SR clinical study there were two (0.9%) patient complaints out of 230 follow-up visits. Both complaints originated from the same patient who felt palpitations during periods of rapid arm movements. The sensor gain was subsequently reprogrammed to a lower level and retested during a follow-up. Additionally, this patient had an exercise test and twenty-four hour Holter recording demonstrating appropriate rate adaption. During a subsequent follow-up, the patient again reported feeling palpitations during sawing and teeth brushing movements. The sensor gain and sensor threshold were reprogrammed to a lower

level and retested with these specific arm movements. There was no rate-adaptive pacing evident. There have been no further complaints from this patient after the second reprogramming

6. Patient Deaths and Device Explants

There were twelve patient deaths during the clinical study. These deaths were evaluated by the investigators and determined to be unrelated to the pacing system. Table 14 provides the specific details of the patient deaths.

Table 14: Patient Deaths

Implant Date	Case	Device	Date Patient Expired	Death Category	Cause of Death
11-08-95	78	Dromos DR 86202326	12-13-95	Cardiac	Cardiac arrest and severe ischemic cardiomyopathy
11-16-95	87	Dromos DR 86202357	02-10-96	Cardiac	Congestive heart failure, cardiomyopathy
11-30-95	97	Dromos DR 86202477	01-21-96	Cardiac	Congestive heart failure, ischemic cardiomyopathy
12-01-95	99	Dromos DR 86202281	05-04-96	Cardiac	Acute myocardial infarction
12-04-95	100	Dromos DR 86202273	04-01-96	Cardiac	Cardiogenic shock secondary to ischemic heart disease
12-15-95	108	Dromos DR 86202192	12-22-95	Cardiac	Progressive congestive heart failure secondary to ischemic and idiopathic cardiomyopathy
12-20-95	110	Dromos DR 86201546	02-05-96	Cardiac	Cardiac arrest. Ventricular fibrillation due to respiratory failure
01-10-96	120	Dromos DR 86202276	04-10-96	Cardiac	Cardiac arrest
01-30-96	143	Dromos DR 86202977	02-21-96	Cardiac	Atherosclerotic heart disease
11-27-95	10002	Dromos SR 85890116	12-31-95	Non-cardiac	Pancreatic Cancer
01-29-96	10020	Dromos SR 85802629	04-01-96	Cardiac	Cardiogenic shock secondary to ischemic heart disease
04-12-96	10042	Dromos SR 85804397	04-22-96	Cardiac	Myocardial Infarction

One Dromos DR was explanted secondary to a late postoperative infection. Table 15 provides the specific details of this explant.

Table 15: Device Explants

Implant Date	Case	Device	Explant Date	Explant Reason
09-12-95	61	86201478	02-01-96	Pulse generator explanted secondary to a late postoperative infection.

8. Patient Follow-up Compliance

Dromos DR

Patients were required to be seen at regular intervals for follow-up for the entire duration of the study. The required follow-ups included a pre-release follow-up, a one-month follow-up, a three-month follow-up, and regular follow-ups every six-months. Note that the three-month follow-up was only required during Phase I of the study. Table 16 provides a summary of the follow-up compliance for all patients both in number and as a percentage of all follow-ups of the given type. No patients have discontinued the study for reasons other than death.

Table 16: Follow-Up Compliance

Follow-up	Number Completed	Number Scheduled	Percentage Completed
Pre-Release	313	313	100%
One-Month	273	277	98.6%
Six-Week	25	25	100%
Three-Month	65	65	100%
Six-Month	141	143	98.6%
Twelve-Month	46	48	95.8%
Eighteen-Month	6	7	85.7%
Total	869	878	98.9%
Interim (unscheduled)	179	N/A	N/A
Total	1048	N/A	N/A

Dromos SR

Patients were required to be seen at regular intervals for follow-up for the entire duration of the study. The required follow-ups included a pre-release follow-up, a one-month follow-up, a three-month follow-up, and regular follow-ups every six-months. Note that the three-month follow-up was only required for patients enrolled in the "focused" portion of the study. Table 17 provides a summary of the follow-up compliance for all patients both in number and as a percentage of all follow-ups of the given type. No patients have discontinued the study for reasons other than death.

Table 17: Follow-Up Compliance

Follow-Up	Number Completed	Number Scheduled	Percentage Completed
Pre-Release	89*	91	98%
One-Month	75	77	97%
Three-Month	21	21	100%
Six-Month	18	18	100%
Total Scheduled	203	205	99%
Interim	27	N/A	N/A
Total	230	N/A	N/A

*Two patients completed the pre-release follow-up after the report cutoff date of July 31, 1996.

9. Programmer and Software Function

Data were collected at each follow-up in which the PMS 1000 System was used in order to assess the function of the PMS 1000 System with the pulse generator. The investigator was asked to record the approximate number of programmer uses at each follow-up and to document on the data forms any inappropriate programmer function. A programmer use was defined as any interaction between the programmer and the pulse generator. Examples of such interactions include interrogation of programmed parameters, transmission of programmed parameters, retrieval of lead and battery status, and transmission of intracardiac electrograms. Throughout the duration of the study, there were 15,040 programmer interactions during 1011 Dromos DR and SR follow-ups. There were 7 programmer-related events that occurred. This corresponds to a rate of 0.05% per interaction or 0.69% per procedure. All programmer events were resolved; none of the events adversely affected any of the patients. The PMS 1000 Programming and Monitoring System together with the SWM Software Module (versions C02.C02.U and C03.C02.U) has demonstrated a low event rate and no adverse effects were caused by interaction with the pulse generators.

XI. CONCLUSIONS DRAWN FROM THE STUDIES

Dromos DR

The primary objective of the study was to determine whether the Dromos DR is a safe and effective cardiac pulse generator.

- All patients who completed the six-week follow-up exercise testing showed appropriate rate increase during the initial stages of exercise and an appropriate rate decrease following the cessation of exercise in the DDDR pacing mode. There were no reports of unexpected sensor behavior during any of the exercise tests or sensor parameter optimizations

- Analyses of the twenty-four hour Holter recordings taken at the one-month follow-up revealed some pacing and sensing abnormalities (45%). The Dromos DR pulse generator has programmable values and features used to resolve most of the Holter recording findings. None of the abnormalities that could not be resolved through pulse generator adjustment (7%) resulted in patient complaints or symptoms or required further action.
- There were no complications resulting from inappropriate patient / pulse generator interaction reported by the investigator that were related to device malfunction during required follow-up evaluations. There were 93 (8.9%) follow-ups out of 1048 follow-ups where an adverse event was reported. All of these events were either clinically insignificant or were resolved by the investigator through reprogramming, drug therapy or other medical interventions.
- Interaction of the PMS 1000 Programming and Monitoring System and associated software (SWM 1000, version C02.C02.U) with the Dromos DR including interrogation, programming, and the use of other features was reliable. Only two instances out of 12,617 interactions (0.02%) or 808 follow-ups (0.2%) could not be resolved by additional training. All programmer events were resolved; none of the events adversely affected any of the patients.
- There have been no reports of clinical issues related to the chronic use of the device. The eleven patient deaths in the study have not been related to the pulse generator. The one device explant was secondary to a late postoperative infection.

The secondary objective of the study was to determine whether the DDDR pacing mode available in the pacing system provides a clinical benefit over standard DDD pacing for patients with chronotropic incompetence.

- Analyses of all five clinical benefit endpoints, including maximum oxygen consumption, oxygen consumption at anaerobic threshold, total exercise time, exercise time at anaerobic threshold, and heart rate at anaerobic threshold showed a statistically significant benefit of the DDDR mode over the DDD mode for those patients classified as chronotropically incompetent that were able to reach anaerobic threshold.

Dromos SR

The primary objective of the study was to determine whether the Dromos SR is a safe and effective single-chamber cardiac pulse generator

- All patients who completed the one-month follow-up exercise testing showed appropriate rate increase, either sensor controlled or intrinsic, during the initial stages

of exercise and an appropriate rate decrease, either sensor controlled or intrinsic, following the cessation of exercise in the SSIR pacing mode. Two patients had their sensor gain adjusted following the exercise testing to further optimize their rate-adaptive parameters. There were no reports of unexpected sensor behavior during any of the exercise tests or sensor parameter optimizations.

- Analyses of the twenty-four hour Holter recordings taken at the one-month follow-up demonstrated normal pacing and sensing behavior in 90.5% of the patients. Only two, or 9.5%, of the Holter recordings showed rare ventricular undersensing. This ventricular undersensing is not related to the Dromos SR, but attributable to pulse generator programming, patient condition, lead position, or other reasons. The Dromos SR has programmable values and features available to resolve all of these Holter recording findings. However, none of these were deemed clinically significant; therefore, reprogramming was not completed. There were no instances (0%) of sensor-driven pacing associated with diary entries noting sleep periods, further supporting the safety of the Dromos SR pulse generator.
- Analyses of daily activity testing completed at the one-month follow-up demonstrated that 19 patients (86.4%) had appropriate sensor-driven pacing which correlated to changing activity levels. Two patients (9.1%) had some sensor-driven pacing noted during standing and one patient (4.5%) had some sensor-driven pacing during a rest period. However, Holter timing errors may have complicated this analysis. The remainder of the twenty-four hour Holter recordings demonstrated normal pacing and sensing behavior according to the ECG recordings. This further supports the possible timing error conclusion.
- There were no complications resulting from inappropriate patient/pulse generator interaction reported by the investigators related to device malfunction during required follow-up evaluations. There were 6 follow-ups out of 230 follow-ups (2.6%) where an adverse event was reported. All of these events were either clinically insignificant or were resolved by the investigator through reprogramming, drug therapy, lead repositioning, or lead replacement. Only one patient (1.0%) had a sensor programming adverse event. This was resolved by reprogramming the rate-adaptive parameters at a subsequent follow-up.
- Interaction of the PMS 1000 Programming and Monitoring System and associated software (SWM 1000, version C03.C02.U) with the Dromos SR including interrogation, programming, and the use of other features was reliable. Throughout the duration of the study, there were 2,423 programmer interactions during 230 follow-ups. There were no (0%) programmer related adverse events that occurred.
- There have been no reports of issues that are related to the chronic use of the device. The three patient deaths in the study were not related to the pulse generator. There have been no device explants.

XII. PANEL RECOMMENDATION

Pursuant to section 515(f) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Circulatory System Devices Panel, an FDA advisory panel, for review and recommendation because the information in the PMA substantially duplicated information previously reviewed by this panel

XIII. CDRH DECISION

FDA issued an approval order on ^{OCT 11 1996} June 28, 1996 and was found to be in compliance with the device Good Manufacturing Practice regulations. The sponsor's manufacturing facility was

XIV. APPROVAL SPECIFICATIONS

Directions for use: See the labeling

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions and Adverse Events in the Labeling

Post-approval Requirements and Restrictions: See approval order

Labeling

includes:

- Outer Box Label
- Medical Device Registration Form (MDRF)
- Return Envelope (for MDRF)
- MDRF Label
- Gas Sterilization
- Quality Assurance Box Seal
- IS-1 Compatibility
- Software Cartridge Label
- Connector/Polarity Identification Dots
- Patient Temporary ID Card
- Pacemaker Warranty
- Routine Explant Form
- Complaint Report Form
- Technical Manuals
 - Dromos DR/DR-A/SR/SR-B
 - SWM 1000/C07.C02.U
 - PMS 1000 Programming and Monitoring System
- Patient Manual "What you should know..."

Outer Box Label - Dromos DR

DROMOS DR

UNI/BIPOLAR PACEMAKER

IS-1 International Standard

ISO 5841-3:1992(E)

DDDR Silicone Coated

Order No. 120 851

Serial No. 1 ~

Use Before 2 ~

Rate 60 ppm

Pulse (A) 4.8 V; 0.5 ms

(V) 4.8 V; 0.5 ms

NOTE: This unit is designed for use with two (2) Unipolar or Bipolar **IS-1** leads meeting the International Standard ISO 5841-3:1992(E). Maximum sterilization temperature 55° C (131° F).

Mode	DDD*
Lower Rate	60 ppm
Hysteresis	OFF
Upper Tracking Rate	160 ppm
UTR Response	2 I
Dynamic AV Delay	MEDIUM
ARP Extension	0
Safety AV Delay	100 ms
Ventricular Blanking Period	24 ms
Dual Demand	OFF
Magnet Rate	90 ppm (10 pulses), Asynch
Pulse Amplitude	(A) 4.8 V; (V) 4.8 V
Pulse Width	(A) 0.5 ms; (V) 0.5 ms
Sensitivity	(A) 1.5 mV; (V) 2.5 mV
Refractory Period	(A) 400 ms; (V) 300 ms
Polarity	Unipolar

*Factory settings For programmable parameters, see enclosed Technical Manual.

STERILE: Pacemaker as identified and accessories

NON-STERILE: Package Inserts

STERILIZATION: Sterility cannot be guaranteed if the package has been damaged during transportation. Please examine the package carefully before opening. If it shows any evidence of damage or mishandling, it should be returned immediately to BIOTRONIK. Once the box seal has been broken, title passes to the hospital and a purchase order is required.

NOTE: This unit has been gas sterilized with ethylene oxide and should not be resterilized by any other means.

CAUTION: Recommended Storage Temperature: 5° C - 55° C (41° F - 131° F).

Federal (U.S.A.) law restricts this device to sale by, or on the order of, a physician.

Made in Germany

L1225-D 8/96

Manufactured by

BIOTRONIK GmbH & Co.
Woermannkehr 1
D-12359 Berlin
Germany

Distributed by:

BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035-5369
(800) 547-0394

Outer Box Label - Dromos DR-A

DROMOS DR-A
UNIPOLAR PACEMAKER
DDDR Silicone Coated

Order No. 120 907
Serial No. 1 ~
Use Before 2 ~
Rate **60 ppm**
Pulse (A) 4.8 V; 0.5 ms
(V) 4.8 V; 0.5 ms

NOTE: This unit is designed for use with two (2) 5 mm Unipolar leads. Maximum sterilization temperature 55° C (131° F).

Mode	DDD*
Lower Rate	60 ppm
Hysteresis	OFF
Upper Tracking Rate	160 ppm
UTR Response	2:1
Dynamic AV Delay	MEDIUM
ARP Extension	0
Safety AV Delay	100 ms
Ventricular Blanking Period	24 ms
Dual Demand	OFF
Magnet Rate	90 ppm (10 pulses), Asynch
Pulse Amplitude	(A) 4.8 V; (V) 4.8 V
Pulse Width	(A) 0.5 ms; (V) 0.5 ms
Sensitivity	(A) 1.5 mV; (V) 2.5 mV
Refractory Period	(A) 400 ms; (V) 300 ms
Polarity	Unipolar

*Factory settings - For programmable parameters, see enclosed Technical Manual.

STERILE: Pacemaker as identified and accessories
NON-STERILE: Package Inserts

STERILIZATION: Sterility cannot be guaranteed if the package has been damaged during transportation. Please examine the package carefully before opening. If it shows any evidence of damage or mishandling, it should be returned immediately to BIOTRONIK. Once the box seal has been broken, title passes to the hospital and a purchase order is required.

NOTE: This unit has been gas sterilized with ethylene oxide and should not be resterilized by any other means.

CAUTION: Recommended Storage Temperature: 5° C - 55° C (41° F - 131° F).

Federal (U.S.A.) law restricts this device to sale by, or on the order of, a physician.

Made in Germany

L1226-C 8/96

Manufactured by:

BIOTRONIK GmbH & Co.
Wiermannkehrstr.
D-12359 Berlin
Germany

Distributed by:

BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035-5369
(800) 547-0394

Outer Box Label - Dromos SR

DROMOS SR

UNI/BIPOLAR PACEMAKER
IS-1 International Standard
ISO 5841-3:1992(E)
SSIR Silicone Coated

Order No. 120 856

Serial No. 1 ~
Use Before 2 ~
Rate 60 ppm
Pulse 4.8 V; 0.5 ms

NOTE: This unit is designed for use with one (1) Unipolar or Bipolar **IS-1** lead meeting the International Standard ISO 5841-3:1992(E). Maximum sterilization temperature 55° C (131° F).

Mode	SSI*
Lower Rate	60 ppm
Hysteresis	OFF
Upper Tracking Rate	160 ppm
Magnet Rate	90 ppm (10 pulses), Asynch
Pulse Amplitude	4.8 V
Pulse Width	0.5 ms
Sensitivity	(A) 2.0 mV; (V) 2.5 mV
Refractory Period	300 ms
Polarity	Unipolar

*Factory settings - For programmable parameters, see enclosed Technical Manual.

STERILE: Pacemaker as identified and accessories

NON-STERILE: Package Inserts

STERILIZATION: Sterility cannot be guaranteed if the package has been damaged during transportation. Please examine the package carefully before opening. If it shows any evidence of damage or mishandling, it should be returned immediately to BIOTRONIK. Once the box seal has been broken, title passes to the hospital and a purchase order is required.

NOTE: This unit has been gas sterilized with ethylene oxide and should not be resterilized by any other means.

CAUTION: Recommended Storage Temperature: 5° C - 55° C (41° F - 131° F).

Federal U.S.A. law restricts the device to sale by, or on the order of, a physician.

Made in Germany

L1227-B 8/96

Manufactured by:

BIOTRONIK GmbH & Co.
Woermannkehre 1
D-12359 Berlin
Germany

Distributed by:

BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035-5369
(800) 547-0394

Outer Box Label - Dromos SR-B

DROMOS SR-B

UNIPOLAR PACEMAKER
SSIR Silicone Coated

Order No. 120 905

Serial No. 1~
Use Before: 2~
Rate: 60 ppm
Pulse: 4.8 V; 0.5 ms

NOTE: This unit is designed for use with a 6 mm unipolar lead only. Included is a PEH Upsizing Sleeve Adapter for use in connecting the 6 mm Dromos SR-B to a 5 mm unipolar lead. Maximum sterilization temperature 55° C (131° F).

Mode	SSI*
Lower Rate	60 ppm
Hysteresis	OFF
Upper Tracking Rate	160 ppm
Magnet Rate	90 ppm (10 pulses), Asynch
Pulse Amplitude	4.8 V
Pulse Width	0.5 ms
Sensitivity	(A) 2.0 mV; (V) 2.5 mV
Refractory Period	300 ms
Polarity	Unipolar

*Factory settings - For programmable parameters, see enclosed Technical Manual.

STERILE: Pacemaker as identified and accessories

NON-STERILE: Package Inserts

STERILIZATION: Sterility cannot be guaranteed if the package has been damaged during transportation. Please examine the package carefully before opening. If it shows any evidence of damage or mishandling, it should be returned immediately to BIOTRONIK. Once the box seal has been broken, title passes to the hospital and a purchase order is required.

NOTE: This unit has been gas sterilized with ethylene oxide and should not be resterilized by any other means.

CAUTION: Recommended Storage Temperature: 5° C - 55° C (41° F - 131° F).

Federal (U.S.A.) law restricts the device to sale by, or on the order of, a physician.

Made in Germany

L1228-B 8/96

Manufactured by:

BIOTRONIK GmbH & Co.
Wormannkehre 1
D-12359 Berlin
Germany

Distributed by:

BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035-5369
(800) 547-0394



BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97138
(800) 547-0394

Medical Device Registration Form

PLEASE FILL OUT FORM COMPLETELY - TYPE OR PRINT FIRMLY

IMPORTANT: This device must be tracked per FDA Regulation. Compliance is mandatory. Failure to comply could result in a violation of FDA law.

Patient Data

LAST NAME _____ INITIAL _____
 FIRST NAME _____
 STREET _____
 CITY _____
 STATE _____ ZIP CODE _____
 PHONE NUMBER () _____
 SEX M F BIRTH DATE ____/____/____
 SOCIAL SECURITY NUMBER _____

Hospital Data

HOSPITAL NAME _____
 STREET _____
 CITY _____
 STATE _____ ZIP CODE _____
 PHONE NUMBER () _____

Pulse Generator Data

MODEL/No. Dromos DR #120851
 SERIAL NUMBER 12345678
 MANUFACTURER BIOTRONIK

WARRANTY PERIOD (from date of implant) _____
 IMPLANT DATE _____

Implanting Physician

LAST NAME _____ INITIAL _____
 FIRST NAME _____
 STREET _____
 CITY _____
 STATE _____ ZIP CODE _____
 PHONE NUMBER () _____
 SPECIALTY: ELECTROPHYSIOLOGIST SURGEON INTERNIST
 CARDIOLOGIST OTHER _____

Ventricular Lead Data

MODEL _____ POLARITY: BIPOLAR UNIPOLAR SINGLE-PASS LEAD
 SERIAL NUMBER _____
 MANUFACTURER _____
 IMPLANT DATE _____
 THRESHOLD PACING _____ V _____ mA
 AT PULSE WIDTH _____ V/s
 P/R AMPLITUDE _____ mV SLEW _____ V/s
 RESISTANCE _____ Ohms

Following Physician

LAST NAME _____ INITIAL _____
 FIRST NAME _____
 STREET _____
 CITY _____
 STATE _____ ZIP CODE _____
 PHONE NUMBER () _____
 SPECIALTY: ELECTROPHYSIOLOGIST SURGEON INTERNIST
 CARDIOLOGIST OTHER _____

Atrial Lead Data

MODEL _____ POLARITY: BIPOLAR UNIPOLAR SINGLE-PASS LEAD
 SERIAL NUMBER _____
 MANUFACTURER _____
 IMPLANT DATE _____
 THRESHOLD PACING _____ V _____ mA
 AT PULSE WIDTH _____ mV
 P/R AMPLITUDE _____ mV SLEW _____ V/s
 RESISTANCE _____ Ohms

Referring Physician

LAST NAME _____ INITIAL _____
 FIRST NAME _____
 STREET _____
 CITY _____
 STATE _____ ZIP CODE _____
 PHONE NUMBER () _____
 SPECIALTY: ELECTROPHYSIOLOGIST SURGEON INTERNIST
 CARDIOLOGIST OTHER _____

Indications (CHECK ALL THAT APPLY)

- SICK SINUS SYNDROME
- SINUS ARREST (PAUSES)
- BRADYCARDIA
- BRADY/TACHY SYNDROME
- AV BLOCK
 - MOBITZ I
 - MOBITZ II
 - COMPLETE HEART BLOCK
- CONGESTIVE HEART FAILURE
- ATRIAL TACHYARRHYTHMIA
- OTHER _____

Programmed Parameters

NOMINAL SETTINGS?: YES NO
 MODE _____
 LOWER RATE _____ ppm
 UPPER RATE _____ ppm
 HYSTERESIS _____ ppm
 AV DELAY: PACE _____ ms
 AV DELAY: SENSE _____ ms
 DYNAMIC AV DELAY: 1 LOW 2 MED 3 HIGH 4 IND
 DUAL DEMAND: 1 ON 2 OFF
 RATE ADAPTATION: 1 ON 2 OFF

BIOTRONIK will NOT enter any settings in patient file, unless specified below.

	ATRIUM	VENTRICLE
PULSE AMPLITUDE:	_____ V	_____ V
PULSE WIDTH:	_____ ms	_____ ms
SENSITIVITY:	_____ mV	_____ mV
REFRACTORY:	_____ ms	_____ ms
BLANKING TIME:	_____ ms	_____ ms
POLARITY		
SENSING	<input type="checkbox"/> 1 UNIPOLAR <input type="checkbox"/> 2 BIPOLAR	<input type="checkbox"/> 1 UNIPOLAR <input type="checkbox"/> 2 BIPOLAR
PACING	<input type="checkbox"/> 1 UNIPOLAR <input type="checkbox"/> 2 BIPOLAR	<input type="checkbox"/> 1 UNIPOLAR <input type="checkbox"/> 2 BIPOLAR

Explanted Device Data

WAS EXPLANT PERFORMED? NO YES → IF A BIOTRONIK DEVICE IS RETURNED, IT MUST BE ACCOMPANIED BY A COMPLETED RETURNED PRODUCT FORM.
 ORIGINAL IMPLANT DATE _____ EXPLANTING PHYSICIAN _____
 MANUFACTURER _____ MODEL _____ SERIAL NUMBER _____

Completed by

SIGNATURE _____ DATE _____ PHONE NUMBER _____
 PRINTED NAME _____

Comments

Biotronik Office use only

HOSPITAL _____
 SALES REPRESENTATIVE _____
 IMPLANTING PHYSICIAN _____
 FOLLOWING PHYSICIAN _____
 REFERRING PHYSICIAN _____
 DATA ENTRY _____
 PATIENT FOLDER _____
 CLERK _____

348



BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035
(800) 547-0394

Medical Device Registration Form

PLEASE FILL OUT FORM COMPLETELY - TYPE OR PRINT FIRMLY

IMPORTANT: This device must be tracked per FDA Regulation. Compliance is mandatory. Failure to comply could result in a violation of FDA law.

Patient Data

LAST NAME _____ INITIAL _____
 FIRST NAME _____
 STREET _____
 CITY _____
 STATE _____ ZIP CODE _____
 PHONE NUMBER (____) _____
 SEX: M F BIRTH DATE ____/____/____
 SOCIAL SECURITY NUMBER _____

Hospital Data

HOSPITAL NAME _____
 STREET _____
 CITY _____
 STATE _____ ZIP CODE _____
 PHONE NUMBER (____) _____

Pulse Generator Data

MODEL/No. **Dromos DR-A #120907**
 SERIAL NUMBER **12345678**
 MANUFACTURER **BIOTRONIK**
 WARRANTY PERIOD (from date of implant) _____
 IMPLANT DATE _____

Implanting Physician

LAST NAME _____ INITIAL _____
 FIRST NAME _____
 STREET _____
 CITY _____
 STATE _____ ZIP CODE _____
 PHONE NUMBER (____) _____
 SPECIALTY: ELECTROPHYSIOLOGIST SURGEON INTERNIST
 CARDIOLOGIST OTHER

Ventricular Lead Data

MODEL _____ POLARITY: BIPOLAR
 SERIAL NUMBER _____ UNIPOLAR
 MANUFACTURER _____ SINGLE-PASS LEAD
 IMPLANT DATE _____
 THRESHOLD PACING _____ mA
 AT PULSE WIDTH _____ ms
 P/R AMPLITUDE _____ V/s EW _____ V/s
 RESISTANCE _____ Ohms

Following Physician

LAST NAME _____ INITIAL _____
 FIRST NAME _____
 STREET _____
 CITY _____
 STATE _____ ZIP CODE _____
 PHONE NUMBER (____) _____
 SPECIALTY: ELECTROPHYSIOLOGIST SURGEON INTERNIST
 CARDIOLOGIST OTHER

Atrial Lead Data

MODEL _____ POLARITY: BIPOLAR
 SERIAL NUMBER _____ UNIPOLAR
 MANUFACTURER _____ SINGLE-PASS LEAD
 IMPLANT DATE _____
 THRESHOLD PACING _____ mA
 AT PULSE WIDTH _____ ms
 P/R AMPLITUDE _____ V/s EW _____ V/s
 RESISTANCE _____ Ohms

Referring Physician

LAST NAME _____ INITIAL _____
 FIRST NAME _____
 STREET _____
 CITY _____
 STATE _____ ZIP CODE _____
 PHONE NUMBER (____) _____
 SPECIALTY: ELECTROPHYSIOLOGIST SURGEON INTERNIST
 CARDIOLOGIST OTHER

Indications (CHECK ALL THAT APPLY)

- SICK SINUS SYNDROME
 - SINUS ARREST (PALSES)
 - BRADYCARDIA
 - BRADY/TACHY SYNDROME
- AV BLOCK
 - MOBITZ I
 - MOBITZ II
 - COMPLETE HEART BLOCK
- CONGESTIVE HEART FAILURE
- ATRIAL TACHYARRHYTHMIA
- OTHER _____

Programmed Parameters

BIOTRONIK will NOT enter any settings in patient file, unless specified below.

NUMINAL SETTINGS?: YES NO

MODE _____	PULSE AMPLITUDE: _____ V
LOWER RATE _____ ppm	PULSE WIDTH: _____ ms
UPPER RATE _____ ppm	SENSITIVITY _____ mV
HYSTERESIS _____ ppm	REFRACTORY _____ ms
AV DELAY PACE _____ ms	BLANKING TIME _____ ms
AV DELAY SENSE _____ ms	POLARITY
DYNAMIC AV DELAY: <input type="checkbox"/> 1 LOW <input type="checkbox"/> 2 MED <input type="checkbox"/> 3 HIGH <input type="checkbox"/> 4 IND	SENSING <input type="checkbox"/> 1 UNIPOLAR <input type="checkbox"/> 1 UNIPOLAR
DUAL DEMAND: <input type="checkbox"/> 1 ON <input type="checkbox"/> 2 OFF	<input type="checkbox"/> 2 BIPOlar <input type="checkbox"/> 2 BIPOlar
RATE ADAPTATION: <input type="checkbox"/> 1 ON <input type="checkbox"/> 2 OFF	PACING <input type="checkbox"/> 1 UNIPOLAR <input type="checkbox"/> 1 UNIPOLAR
	<input type="checkbox"/> 2 BIPOlar <input type="checkbox"/> 2 BIPOlar

Explanted Device Data

WAS EXPLANT PERFORMED?: NO YES → IF A BIOTRONIK DEVICE IS RETURNED, IT MUST BE ACCOMPANIED BY A COMPLETED RETURNED PRODUCT FORM.
 ORIGINAL IMPLANT DATE _____ EXPLANTING PHYSICIAN _____
 MANUFACTURER _____ MODEL _____ SERIAL NUMBER _____

Completed by

SIGNATURE _____ DATE _____ PHONE NUMBER _____
 PRINTED NAME _____

Comments

Biotronik Office use only

HOSPITAL _____
 SALES REPRESENTATIVE _____
 IMPLANTING PHYSICIAN _____
 FOLLOWING PHYSICIAN _____
 REFERRING PHYSICIAN _____
 DATA ENTRY _____
 PATIENT FOLDER _____
 CLERK _____

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IMPORTANT: This device must be tracked per FDA Regulation. Compliance is mandatory. Failure to comply could result in a violation of FDA law.

Patient Data

LAST NAME _____ INITIAL _____
 FIRST NAME _____
 STREET _____
 CITY _____
 STATE _____ ZIP CODE _____
 PHONE NUMBER (____) _____
 SEX: M F BIRTHDATE ____/____/____
 SOCIAL SECURITY NUMBER _____

Pulse Generator Data

MODEL/No. Dromos SR #120856
 SERIAL NUMBER 12345678
 MANUFACTURER BIOTRONIK

WARRANTY PERIOD (from date of implant) _____
 IMPLANT DATE _____

Ventricular Lead Data

MODEL _____ POLARITY: BIPOLAR
 UNIPOLAR
 SINGLE-PASS LEAD
 SERIAL NUMBER _____
 MANUFACTURER _____
 IMPLANT DATE _____
 THRESHOLD PACING _____ V _____ mA
 AT PULSE WIDTH _____ ms
 P/R AMPLITUDE _____ mV SLEW _____ V/s
 RESISTANCE _____ Ohm

Atrial Lead Data

MODEL _____ POLARITY: BIPOLAR
 UNIPOLAR
 SINGLE-PASS LEAD
 SERIAL NUMBER _____
 MANUFACTURER _____
 IMPLANT DATE _____
 THRESHOLD PACING _____ V _____ mA
 AT PULSE WIDTH _____ ms
 P/R AMPLITUDE _____ mV SLEW _____ V/s
 RESISTANCE _____ Ohm

Hospital Data

HOSPITAL NAME _____
 STREET _____
 CITY _____
 STATE _____ ZIP CODE _____
 PHONE NUMBER (____) _____

Implanting Physician

LAST NAME _____ INITIAL _____
 FIRST NAME _____
 STREET _____
 CITY _____
 STATE _____ ZIP CODE _____
 PHONE NUMBER (____) _____
 SPECIALTY: ELECTROPHYSIOLOGIST SURGEON INTERNIST
 CARDIOLOGIST OTHER _____

Following Physician

LAST NAME _____ INITIAL _____
 FIRST NAME _____
 STREET _____
 CITY _____
 STATE _____ ZIP CODE _____
 PHONE NUMBER (____) _____
 SPECIALTY: ELECTROPHYSIOLOGIST SURGEON INTERNIST
 CARDIOLOGIST OTHER _____

Referring Physician

LAST NAME _____ INITIAL _____
 FIRST NAME _____
 STREET _____
 CITY _____
 STATE _____ ZIP CODE _____
 PHONE NUMBER (____) _____
 SPECIALTY: ELECTROPHYSIOLOGIST SURGEON INTERNIST
 CARDIOLOGIST OTHER _____

Indications (CHECK ALL THAT APPLY)

- SICK SINUS SYNDROME
 - SINUS ARREST (PAUSES)
 - BRADYCARDIA
 - BRADY/TACH SYNDROME
- AV BLOCK
 - MOBITZ I
 - MOBITZ II
 - COMPLETE HEART BLOCK
- CONGESTIVE HEART FAILURE
- ATRIAL TACHYARRHYTHMIA
- OTHER _____

Programmed Parameters

NOMINAL SETTINGS? YES NO
 MODE _____
 LOWER RATE _____ ppm
 UPPER RATE _____ ppm
 HYSTERESIS _____ ppm
 AV DELAY: PACE _____ ms
 AV DELAY: SENSE _____ ms
 DYNAMIC AV DELAY: 1 LOW 2 MED 3 HIGH 4 INC.
 DUAL DEMAND: 1 ON 2 OFF
 RATE ADAPTATION: 1 ON 2 OFF

BIOTRONIK will NOT enter any settings in patient file, unless specified below.

	ATRIUM	VENTRICLE
PULSE AMPLITUDE:	_____ V	_____ V
PULSE WIDTH:	_____ ms	_____ ms
SENSITIVITY:	_____ mV	_____ mV
REFRACTORY:	_____ ms	_____ ms
BLANKING TIME:	_____ ms	_____ ms
POLARITY		
SENSING	<input type="checkbox"/> 1 UNIPOLAR <input type="checkbox"/> 2 BIPOLAR	<input type="checkbox"/> 1 UNIPOLAR <input type="checkbox"/> 2 BIPOLAR
PACING	<input type="checkbox"/> 1 UNIPOLAR <input type="checkbox"/> 2 BIPOLAR	<input type="checkbox"/> 1 UNIPOLAR <input type="checkbox"/> 2 BIPOLAR

Explanted Device Data

WAS EXPLANT PERFORMED?: NO YES → IF A BIOTRONIK DEVICE IS RETURNED IT MUST BE ACCOMPANIED BY A COMPLETED RETURNED PRODUCT FORM.
 ORIGINAL IMPLANT DATE _____ EXPLANTING PHYSICIAN _____
 MANUFACTURER _____ MODEL _____ SERIAL NUMBER _____

Completed by

SIGNATURE _____ DATE _____ PHONE NUMBER _____
 PRINTED NAME _____

Comments

Biotronik Office use only

HOSPITAL _____
 SALES REPRESENTATIVE _____
 IMPLANTING PHYSICIAN _____
 FOLLOWING PHYSICIAN _____
 REFERRING PHYSICIAN _____
 DATA ENTRY _____
 PATIENT FOLDER _____
 CLERK _____



BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97031
(800) 547-0391

Medical Device Registration Form

PLEASE FILL OUT FORM COMPLETELY - TYPE OR PRINT FIRMLY

IMPORTANT: This device must be tracked per FDA Regulation. Compliance is mandatory. Failure to comply could result in a violation of FDA law.

Patient Data

LAST NAME _____ INITIAL _____
 FIRST NAME _____
 STREET _____
 CITY _____
 STATE _____ ZIP CODE _____
 PHONE NUMBER (____) _____
 SEX: M F BIRTH DATE: ____/____/____
 SOCIAL SECURITY NUMBER _____

Hospital Data

HOSPITAL NAME _____
 STREET _____
 CITY _____
 STATE _____ ZIP CODE _____
 PHONE NUMBER (____) _____

Pulse Generator Data

MODEL/No. Dromos SR-B #120905
 SERIAL NUMBER 12345678
 MANUFACTURER BIOTRONIK
 WARRANTY PERIOD (from date of implant) _____
 IMPLANT DATE _____

Implanting Physician

LAST NAME _____ INITIAL _____
 FIRST NAME _____
 STREET _____
 CITY _____
 STATE _____ ZIP CODE _____
 PHONE NUMBER (____) _____
 SPECIALTY: ELECTROPHYSIOLOGIST SURGEON INTERNIST
 CARDIOLOGIST OTHER _____

Ventricular Lead Data

MODEL _____
 SERIAL NUMBER _____
 MANUFACTURER _____
 IMPLANT DATE _____
 POLARITY:
 BIPOLAR
 UNIPOLAR
 SINGLE-PASS LEAD
 THRESHOLD PACING _____ mA
 AT PULSE WIDTH _____ ms
 P/R AMPLITUDE _____ mV SLEW _____ V/s
 RESISTANCE _____ Ohms

Following Physician

LAST NAME _____ INITIAL _____
 FIRST NAME _____
 STREET _____
 CITY _____
 STATE _____ ZIP CODE _____
 PHONE NUMBER (____) _____
 SPECIALTY: ELECTROPHYSIOLOGIST SURGEON INTERNIST
 CARDIOLOGIST OTHER _____

Atrial Lead Data

MODEL _____
 SERIAL NUMBER _____
 MANUFACTURER _____
 IMPLANT DATE _____
 POLARITY:
 BIPOLAR
 UNIPOLAR
 SINGLE-PASS LEAD
 THRESHOLD PACING _____ mA
 AT PULSE WIDTH _____ ms
 P/R AMPLITUDE _____ mV SLEW _____ V/s
 RESISTANCE _____ Ohms

Referring Physician

LAST NAME _____ INITIAL _____
 FIRST NAME _____
 STREET _____
 CITY _____
 STATE _____ ZIP CODE _____
 PHONE NUMBER (____) _____
 SPECIALTY: ELECTROPHYSIOLOGIST SURGEON INTERNIST
 CARDIOLOGIST OTHER _____

Indications (CHECK ALL THAT APPLY)

- SICK SINUS SYNDROME
- SINUS ARREST (PAUSES)
- BRADYCARDIA
- BRADY/TACHY SYNDROME
- AV BLOCK
- MOBITZ I
- MOBITZ II
- COMPLETE HEART BLOCK
- CONGESTIVE HEART FAILURE
- ATRIAL TACHYARRHYTHMIA
- OTHER _____

Programmed Parameters

BIOTRONIK will NOT enter any settings in patient file, unless specified below.

NOMINAL SETTINGS? YES NO

MODE _____

LOWER RATE _____ ppm	PULSE AMPLITUDE: _____ V
UPPER RATE _____ ppm	PULSE WIDTH: _____ ms
HYSTERESIS _____ ppm	SENSITIVITY: _____ mV
AV DELAY PACE _____ ms	REFRACTORY: _____ ms
AV DELAY SENSE _____ ms	BLANKING TIME _____ ms
DYNAMIC AV DELAY: <input type="checkbox"/> 1 LOW <input type="checkbox"/> 2 MED <input type="checkbox"/> 3 HIGH <input type="checkbox"/> 4 INF	POLARITY:
DUAL DEMAND: <input type="checkbox"/> 1 ON <input type="checkbox"/> 2 OFF	SENSING: <input type="checkbox"/> 1 UNIPOLAR <input type="checkbox"/> 2 BIPOLAR
RATE ADAPTATION: <input type="checkbox"/> 1 ON <input type="checkbox"/> 2 OFF	PACING: <input type="checkbox"/> 1 UNIPOLAR <input type="checkbox"/> 2 BIPOLAR

Explanted Device Data

WAS EXPLANT PERFORMED: NO YES → IF A BIOTRONIK DEVICE IS RETURNED IT MUST BE ACCOMPANIED BY A COMPLETED RETURNED PRODUCT FORM.

ORIGINAL IMPLANT DATE _____ EXPLANTING PHYSICIAN _____
 MANUFACTURER _____ MODEL _____ SERIAL NUMBER _____

Completed by

SIGNATURE _____ DATE _____ PHONE NUMBER _____
 PRINTED NAME _____

Comments

Biotronik Office use only

HOSPITAL _____
 SALES REPRESENTATIVE _____
 IMPLANTING PHYSICIAN _____
 FOLLOWING PHYSICIAN _____
 REFERRING PHYSICIAN _____
 DATA ENTRY _____
 PATIENT FOLDER _____
 CLERK _____

PATIENT REGISTRATION
FORM ENCLOSED

BUSINESS REPLY MAIL
FIRST CLASS PERMIT NO. 274 LAKE OSWEGO, OR

POSTAGE WILL BE PAID BY ADDRESSEE

BIOTRONIK, INC.

6024 JEAN ROAD
LAKE OSWEGO OR 97035-9813



NO POSTAGE
NECESSARY
IF MAILED
IN THE
UNITED STATES



MDRF Return Envelope
(Used in conjunction with Medical Device Registration Form)

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BIOTRONIK Product Identification Information

Dromos DR - Serial Number: 00000000

Model Name / Number: Dromos DR / 120 851
Serial Number: 00000000
Manufacturer Name / Number: BIOTRONIK / 004

Model Name / Number: Dromos DR / 120 851
Serial Number: 00000000
Manufacturer Name / Number: BIOTRONIK / 004

Model Name / Number: Dromos DR / 120 851
Serial Number: 00000000
Manufacturer Name / Number: BIOTRONIK / 004

Model Name / Number: Dromos DR / 120 851
Serial Number: 00000000
Manufacturer Name / Number: BIOTRONIK / 004

Model Name / Number : Dromos DR / 120 851
Serial Number: 00000000
Manufacturer Name / Number: BIOTRONIK / 004

Model Name / Number : Dromos DR / 120 851
Serial Number: 00000000
Manufacturer Name / Number: BIOTRONIK / 004

Apply one label to the **Device Section** on each page of the **BIOTRONIK Medical Device Registration Form**, on the patient's medical record, and/or on any other non-BIOTRONIK device registration form. L1250-A 3/94

BIOTRONIK Product Identification Information

Dromos DR-A - Serial Number: 00000000

Model Name / Number: Dromos DR-A / 120 907
Serial Number: 00000000
Manufacturer Name / Number: BIOTRONIK / 004

Model Name / Number: Dromos DR-A / 120 907
Serial Number: 00000000
Manufacturer Name / Number: BIOTRONIK / 004

Model Name / Number: Dromos DR-A / 120 907
Serial Number: 00000000
Manufacturer Name / Number: BIOTRONIK / 004

Model Name / Number: Dromos DR-A / 120 907
Serial Number: 00000000
Manufacturer Name / Number: BIOTRONIK / 004

Model Name / Number : Dromos DR-A / 120 907
Serial Number: 00000000
Manufacturer Name / Number: BIOTRONIK / 004

Model Name / Number : Dromos DR-A / 120 907
Serial Number: 00000000
Manufacturer Name / Number: BIOTRONIK / 004

Apply one label to the **Device Section** on each page of the **BIOTRONIK Medical Device Registration Form**, on the patient's medical record, and/or on any other non-BIOTRONIK device registration form. L1250-A 3/94

(Used in conjunction with Medical Device Registration Form)

MDRF Labels

Dromos DR/DR-A

BIOTRONIK Product Identification Information

Dromos SR - Serial Number: 00000000

Model Name / Number: Dromos SR / 120 856
Serial Number: 00000000
Manufacturer Name / Number: BIOTRONIK / 004

Model Name / Number: Dromos SR / 120 856
Serial Number: 00000000
Manufacturer Name / Number: BIOTRONIK / 004

Model Name / Number: Dromos SR / 120 856
Serial Number: 00000000
Manufacturer Name / Number: BIOTRONIK / 004

Model Name / Number: Dromos SR / 120 856
Serial Number: 00000000
Manufacturer Name / Number: BIOTRONIK / 004

Model Name / Number: Dromos SR / 120 856
Serial Number: 00000000
Manufacturer Name / Number: BIOTRONIK / 004

Model Name / Number: Dromos SR / 120 856
Serial Number: 00000000
Manufacturer Name / Number: BIOTRONIK / 004

Apply one label to the **Device Section** on each page of the **BIOTRONIK Medical Device Registration Form**, on the patient's medical record, and/or on any other non-BIOTRONIK device registration form. L1250-A 3/94

BIOTRONIK Product Identification Information

Dromos SR-B - Serial Number: 00000000

Model Name / Number: Dromos SR-B / 120 905
Serial Number: 00000000
Manufacturer Name / Number: BIOTRONIK / 004

Model Name / Number: Dromos SR-B / 120 905
Serial Number: 00000000
Manufacturer Name / Number: BIOTRONIK / 004

Model Name / Number: Dromos SR-B / 120 905
Serial Number: 00000000
Manufacturer Name / Number: BIOTRONIK / 004

Model Name / Number: Dromos SR-B / 120 905
Serial Number: 00000000
Manufacturer Name / Number: BIOTRONIK / 004

Model Name / Number: Dromos SR-B / 120 905
Serial Number: 00000000
Manufacturer Name / Number: BIOTRONIK / 004

Model Name / Number: Dromos SR-B / 120 905
Serial Number: 00000000
Manufacturer Name / Number: BIOTRONIK / 004

Apply one label to the **Device Section** on each page of the **BIOTRONIK Medical Device Registration Form**, on the patient's medical record, and/or on any other non-BIOTRONIK device registration form. L1250-A 3/94

(Used in conjunction with Medical Device Registration Form)

Dromos SR/SR-B

MDRF Labels

Other Labeling

Gas Sterilization*

This unit has been gas sterilized

We cannot, however, guarantee that sterility has been maintained if the package has been ruptured in transit. Please examine the package carefully before opening and resterilize if it shows evidence of rupture or rough handling. Use ethylene oxide gas. Maximum sterilization temperature: 55°C (130°F)

Sterile, single use only

Date of sterilization:

Use before:



BIOTRONIK GmbH & Co., Wozzenmühlstr. 1, D-12159 Berlin
Tel. (030) 689 05 0, Telex 1 85 757 bio d, Telefax (030) 684 40 60

**Applied by Manufacturer*

Quality Assurance Box Seal

BIOTRONIK, Inc.
will not consider this
item for restock or credit
if this seal is broken.



"Caution" IS-1 Compatibility*

CAUTION: Because of the numerous available 3.2 mm configurations, e.g., the IS-1 and VS 1 standards, lead/pulse generator compatibility should be confirmed with the pulse generator and/or lead manufacturer *prior* to the implantation of a pacing system.

L1138-C 7/94

**for Dromos DR and Dromos SR only*

SW Cartridge Label

SWM 1000 / C07.C02.U

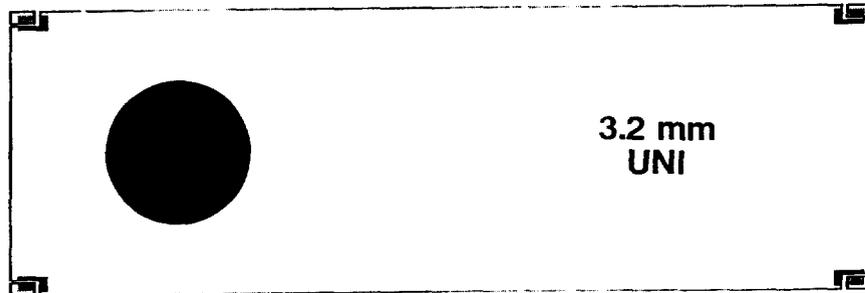
Diplos 05/M05	Nanos
Dromos DR/DR-A/SR/SR-B	Neos 01/02/M 01/LP 01
Gemnos	Pikos LP 01/LP E01
Gemnos 04/04 A	Pikos 01/01-A/E01/E01 B
Gemnos TC 04	Trios M 01/02
Mikros 02	

L1259-A 4/96

Connector/Polarity Identification

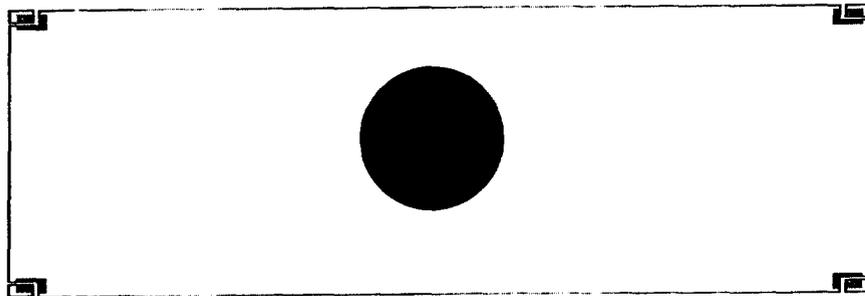
Dromos DR and Dromos SR

3.2 mm Bipolar (red dot)
3.2 mm Unipolar (yellow dot)



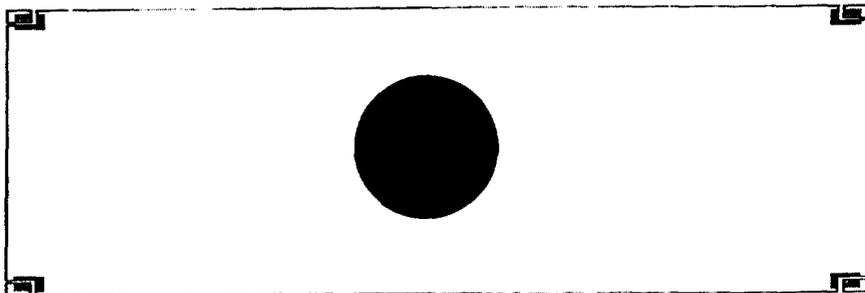
Dromos DR-A

5 mm (blue dot)



Dromos SR-B

6 mm (green dot)



Patient Temporary ID Card

Dromos DR / DR-A

PACEMAKER PATIENT IDENTIFICATION CARD

NAME : _____

ADDRESS : _____

CITY : _____ STATE _____ ZIP _____

PHONE : (____) _____

IMPLANTING PHYS (____) _____ NAME _____

FOLLOWING PHYS (____) _____ NAME _____

PACEMAKER MODEL SERIAL NO. IMPLANT DATE
Dromos DR 1234567 _____

LEAD DATA:
ATRIAL MODEL : _____ S/N. _____

LEAD POLARITY : _____ BIPOLAR _____ UNIPOLAR

VENTRICULAR MODEL : _____ S/N. _____

LEAD POLARITY : _____ BIPOLAR _____ UNIPOLAR



BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035
800-547-0394 (24-hour)
C4100-C 7/94

PACEMAKER PATIENT IDENTIFICATION CARD

NAME : _____

ADDRESS : _____

CITY : _____ STATE _____ ZIP _____

PHONE : (____) _____

IMPLANTING PHYS (____) _____ NAME _____

FOLLOWING PHYS (____) _____ NAME _____

PACEMAKER MODEL SERIAL NO. IMPLANT DATE
Dromos DR-A 123456789 _____

LEAD DATA:
ATRIAL MODEL : _____ S/N. _____

LEAD POLARITY : _____ BIPOLAR _____ UNIPOLAR

VENTRICULAR MODEL : _____ S/N. _____

LEAD POLARITY : _____ BIPOLAR _____ UNIPOLAR



BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035
800-547-0394 (24-hour)
C4100-C 7/94

Patient Temporary ID Card

Dromos SR / SR-B

PACEMAKER PATIENT IDENTIFICATION CARD

NAME : _____
ADDRESS : _____
CITY : _____ STATE _____ ZIP _____
PHONE : (____) _____
IMPLANTING PHYS (____) _____ NAME _____
FOLLOWING PHYS (____) _____ NAME _____

PACEMAKER MODEL SERIAL NO. IMPLANT DATE
Dromos SR-B 123456789 _____

LEAD DATA:
ATRIAL MODEL : _____ S/N. _____
LEAD POLARITY : ___ BIPOLAR ___ UNIPOLAR
VENTRICULAR MODEL : _____ S/N. _____
LEAD POLARITY : ___ BIPOLAR ___ UNIPOLAR



BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035
(800) 547-0394 (24-hour)
C4100-C 7/94

PACEMAKER PATIENT IDENTIFICATION CARD

NAME : _____
ADDRESS : _____
CITY : _____ STATE _____ ZIP _____
PHONE : (____) _____
IMPLANTING PHYS (____) _____ NAME _____
FOLLOWING PHYS (____) _____ NAME _____

PACEMAKER MODEL SERIAL NO. IMPLANT DATE
Dromos SR 1234567 _____

LEAD DATA:
ATRIAL MODEL : _____ S/N. _____
LEAD POLARITY : ___ BIPOLAR ___ UNIPOLAR
VENTRICULAR MODEL : _____ S/N. _____
LEAD POLARITY : ___ BIPOLAR ___ UNIPOLAR



BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035
(800) 547-0394 (24-hour)
C4100-C 7/94



IMPLANTABLE PULSE GENERATOR REPLACEMENT CREDIT POLICY AND LIMITED WARRANTY

BIOTRONIK, Inc. (hereinafter referred to as "BIOTRONIK") warrants, subject to the terms and limitations of this Warranty, that BIOTRONIK's implantable pulse generators are free from manufacturing defects in materials and workmanship. This Warranty is offered for the BIOTRONIK implantable pulse generator model in the event of its malfunction or battery depletion, which was caused by a manufacturing defect within the specified Warranty Time. Malfunctions or battery depletions caused by defective leads are specifically excluded.

The Warranty Time starts at the date of implant. If replacement is required due to device malfunction within the specified Warranty Time, BIOTRONIK will extend a replacement credit equal to the original purchase price of the implanted pulse generator.

In addition, up to \$600 will be paid directly to the patient for surgical fees and hospital expenses incidental to replacement surgery, which are not reimbursed by any third party, including governmental agencies. Upon BIOTRONIK's receipt of itemized statements within six months of the replacement surgery date, payment will be made against such respective invoices, which show verification of the unreimbursed balance still owed by the patient.

This Warranty is for the original pulse generator and must meet the following terms:

- 1) The implantable pulse generator was stored, handled, and implanted in accordance with BIOTRONIK's specifications.
- 2) The explanted pulse generator was replaced with another BIOTRONIK unit, and the explanted unit was returned to BIOTRONIK within 30 days of explant to verify that the unit ceased to function because of malfunction. All devices returned become the property of BIOTRONIK. All available documentation of device malfunction should be included.
- 3) This Warranty shall apply only to the patient registered with BIOTRONIK. Receipt of the completed *Patient Registration Form* serves as verification of implantation.

IMPLANTABLE PULSE GENERATORS CARRY A 60-MONTH REPLACEMENT CREDIT POLICY AND LIMITED WARRANTY.

Upon implantation, the pulse generator, lead(s), and adapter(s), become part of the interdependent pacemaking system, which includes the physiological environment in which these devices must function. Because of the inherent differences in the physical condition of patients, no representation or warranty is made that the body will not adversely react to the system, or that the implantable pulse generator was suitable for treatment of the patient.

THESE PROVISIONS ARE INTENDED TO STATE ALL OF THE RIGHTS AND RESPONSIBILITIES BETWEEN BIOTRONIK, ITS REPRESENTATIVE(S), AND THE PATIENT. THIS WARRANTY IS THE PATIENT'S SOLE AND EXCLUSIVE REMEDY AGAINST EITHER BIOTRONIK OR ITS REPRESENTATIVE(S). NEITHER BIOTRONIK NOR ITS REPRESENTATIVE(S) MAKE ANY OTHER WARRANTY, EXPRESS OR IMPLIED, AS TO THE PERFORMANCE OR LIFE OF THIS IMPLANTABLE PULSE GENERATOR, WHETHER OF MERCHANTABILITY, FITNESS FOR A PARTICULAR USE, OR OTHERWISE, THAT EXTENDS BEYOND THE WARRANTY TIME LISTED ABOVE.

EXCEPT AS EXPRESSLY PROVIDED BY THIS WARRANTY, NEITHER BIOTRONIK NOR ITS REPRESENTATIVE(S) IS RESPONSIBLE FOR ANY LOSS, DAMAGE, OR INJURY OF ANY NATURE, WHETHER DIRECT, INCIDENTAL, OR CONSEQUENTIAL, IN CONNECTION WITH, OR RESULTING FROM THE USE OF THE IMPLANTABLE PULSE GENERATOR, WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, TORT, OR OTHERWISE. SOME STATES DO NOT ALLOW LIMITATION ON HOW LONG AN IMPLIED WARRANTY LASTS, OR THE EXCLUSION OR LIMITATION OF INCIDENTAL OR CONSEQUENTIAL DAMAGES; THEREFORE, THE ABOVE LIMITATION OR EXCLUSION MAY NOT APPLY TO THE PATIENT.

This Warranty gives the patient specific legal rights and is offered for implantable BIOTRONIK pulse generators sold in the United States only. The patient may also have other legal rights which may vary from state to state.

BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035-5369
(800) 547-0394

THIS SIDE IS NOT FOR REPORTING DEVICE MALFUNCTIONS – THIS FORM IS FOR BIOTRONIK DEVICES BEING RETURNED FOR ROUTINE EVALUATION. DEVICES RETURNED TO BIOTRONIK MUST BE ACCOMPANIED BY THIS COMPLETED FORM AND ANY SUPPLEMENTAL DOCUMENTATION. IF THERE IS ASSUMED OR POSSIBLE DEVICE MALFUNCTION, USE THE COMPLAINT REPORT FORM (SEE REVERSE SIDE). PLEASE PRINT OR TYPE. FOR ASSISTANCE, CALL 1-800-547-0394.

Patient / Physician Information

PATIENT'S NAME (FIRST) (MIDDLE) (LAST)			SOCIAL SECURITY NUMBER	
PHYSICIAN'S NAME			TELEPHONE NUMBER	
PHYSICIAN'S STREET ADDRESS		CITY	STATE	ZIP CODE
HOSPITAL			TELEPHONE NUMBER	
HOSPITAL STREET ADDRESS		CITY	STATE	ZIP CODE

Removed Device Information

MODEL NUMBER	SERIAL NUMBER	IMPLANT DATE (MO/DY/YR)	EXPLANT DATE (MO/DY/YR)	
WAS THE REMOVED UNIT REPLACED WITH A UNIT MANUFACTURED BY BIOTRONIK? <input type="checkbox"/> YES <input type="checkbox"/> NO				
IF YES, INDICATE REPLACEMENT MODEL:		SERIAL NUMBER:		
WERE THE LEADS: <input type="checkbox"/> RE-USED <input type="checkbox"/> REPOSITIONED <input type="checkbox"/> REPAIRED <input type="checkbox"/> REPLACED				
MEASURED IMPEDANCE OF OLD OR RE-USED LEAD: ATRIAL LEAD = _____ Ω VENTRICULAR LEAD = _____ Ω				
REASON FOR REMOVAL <input type="checkbox"/> OPENED – NOT IMPLANTED – EXPOSED TO BODILY FLUIDS? <input type="checkbox"/> YES <input type="checkbox"/> NO				
<input type="checkbox"/> PATIENT EXPIRED, NON-PACER RELATED <input type="checkbox"/> ELECTIVE UPGRADE <input type="checkbox"/> INFECTION <input type="checkbox"/> EROSION <input type="checkbox"/> ERI		<input type="checkbox"/> OTHER (DESCRIBE):		
ERI PULSE GENERATOR ERI WAS DETERMINED BY:				
<input type="checkbox"/> RATE DECLINE TO _____ ppm				
<input type="checkbox"/> TELEMETRY: CELL VOLTAGE = _____ V CELL IMPEDANCE = _____ kΩ				
PROGRAMMED SETTINGS OF EXPLANTED PACEMAKER				
	PULSE AMPLITUDE	PULSE WIDTH	SENSITIVITY	PACING
ATRIAL	V	ms	mV	RATE _____ ppm
VENTRICULAR	V	ms	mV	MODE _____
COMMENTS				
FOR ADDITIONAL INFORMATION, PLEASE CONTACT				TELEPHONE NUMBER
FORM COMPLETED BY (PRINTED NAME)			SIGNATURE	DATE

THIS SIDE IS NOT FOR ROUTINE DEVICE RETURNS — THIS FORM IS FOR BIOTRONIK DEVICES BEING RETURNED FOR MALFUNCTION EVALUATION. DEVICES RETURNED TO BIOTRONIK MUST BE ACCOMPANIED BY THIS COMPLETED FORM AND ANY SUPPLEMENTAL DOCUMENTATION. IF THERE IS NO SUSPICION OF DEVICE MALFUNCTION, USE THE ROUTINE EXPLANT FORM (SEE REVERSE SIDE). PLEASE PRINT OR TYPE. FOR ASSISTANCE, CALL 1-800-547-0394.

Patient / Physician Information

PATIENT'S NAME (FIRST) (MIDDLE) (LAST)			SOCIAL SECURITY NUMBER	
PHYSICIAN'S NAME			TELEPHONE NUMBER	
PHYSICIAN'S STREET ADDRESS		CITY	STATE	ZIP CODE
HOSPITAL			TELEPHONE NUMBER	
HOSPITAL STREET ADDRESS		CITY	STATE	ZIP CODE

Removed Device Information

MODEL NUMBER	SERIAL NUMBER	IMPLANT DATE (MO/YR)	EXPLANT DATE (MO/YR)
--------------	---------------	----------------------	----------------------

WAS THE REMOVED UNIT REPLACED WITH A UNIT MANUFACTURED BY BIOTRONIK? YES NO

IF YES, INDICATE REPLACEMENT MODEL:

SERIAL NUMBER:

WERE THE LEADS: RE-USED REPOSITIONED REPAIRED REPLACED

MEASURED IMPEDANCE OF OLD OR RE-USED LEAD: ATRIAL LEAD = _____ Ω VENTRICULAR LEAD = _____ Ω

DEVICE MALFUNCTION (CHECK ALL THAT APPLY)

PLEASE ENCLOSE DOCUMENTATION AND TELEMETRY STRIPS

- | | | |
|--------------------------|--------------------------|------------------------------|
| ATRIAL | VENTRICULAR | |
| <input type="checkbox"/> | <input type="checkbox"/> | INTERMITTANT OUTPUT |
| <input type="checkbox"/> | <input type="checkbox"/> | NO OUTPUT |
| <input type="checkbox"/> | <input type="checkbox"/> | INTERMITTANT LOSS OF CAPTURE |
| <input type="checkbox"/> | <input type="checkbox"/> | TOTAL LOSS OF CAPTURE |
| <input type="checkbox"/> | <input type="checkbox"/> | INTERMITTANT UNDERSENSING |
| <input type="checkbox"/> | <input type="checkbox"/> | TOTAL LOSS OF SENSING |
| <input type="checkbox"/> | <input type="checkbox"/> | INTERMITTANT OVERSENSING |
| <input type="checkbox"/> | <input type="checkbox"/> | CONNECTOR PROBLEM |
| <input type="checkbox"/> | <input type="checkbox"/> | LEAD PROBLEM |

- PECTORAL STIMULATION DIAPHRAGMATIC STIMULATION
- PROGRAMMING: FAILURE TO PROGRAM DIFFICULTY PROGRAMMING
WHICH PARAMETERS?: _____
- TELEMETRY: UNABLE TO OBTAIN DIFFICULT TO OBTAIN
WHICH PARAMETERS?: _____
- OTHER (SPECIFY): _____

PATIENT CONDITION

PATIENT EXPIRED PRODUCT RELATED? YES NO (←IF NEITHER BOX IS CHECKED, DEATH WILL BE PRESUMED UNRELATED TO PRODUCT)

CLINICAL CONSEQUENCES OR CAUSE OF DEATH:

COMMENTS

FOR ADDITIONAL INFORMATION, PLEASE CONTACT

TELEPHONE NUMBER

FORM COMPLETED BY (PRINTED NAME)

SIGNATURE

DATE

Handwritten mark

Dromos DR/DR-A/SR/SR-B Manual

M3039-D 8/96

Dromos

Multiprogrammable, Rate Adaptive
Implantable Pulse Generators

Dromos DR
Unipolar/Bipolar Dual-Chamber

Dromos DR-A
Unipolar Dual-Chamber

Dromos SR
Unipolar/Bipolar Single-Chamber

Dromos SR-B
Unipolar Single-Chamber

TECHNICAL MANUAL

 **BIOTRONIK**

SWM C07.C02.U Technical Manual

M3086-B 8/96

SWM 1000/C07.C02.U

Software Module for PMS 1000

For programming:

Diplos 05/M 05
Dromos DR/DR-A
Dromos SR/SR-B
Gemnos
Gemnos 04/04-A
Gemnos TC 04

Mikros 02
Nanos
Neos 01/02/M 01/LP 01
Pikos LP 01/LP E 01
Pikos 01/01-A/E 01/E 01-B
Trilos M 01/02

Technical Manual

 **BIOTRONIK**

PMS 1000 Programmer Manual

M3038-B 1/96

PMS 1000

Programming and Monitoring System

TECHNICAL MANUAL

 **BIOTRONIK**

Dromos

Multiprogrammable, Rate Adaptive
Implantable Pulse Generators

Dromos DR

Unipolar/Bipolar Dual-Chamber

Dromos DR-A

Unipolar Dual-Chamber

Dromos SR

Unipolar/Bipolar Single-Chamber

Dromos SR-B

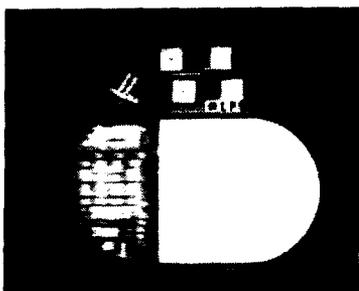
Unipolar Single-Chamber

Technical Manual

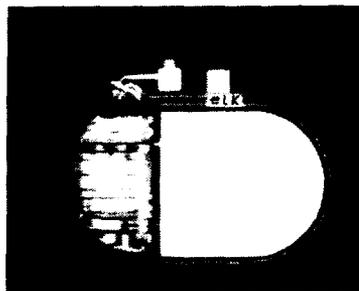
 **BIOTRONIK**

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Dromos DR / DR-A / SR / SR-B
DDDR / SSIR Implantable Pulse Generators



Dromos DR/DR-A X-Ray identification



Dromos SR/SR-B X-Ray identification

Radiopaque Identification

A radiopaque identification code is visible on standard x-ray, and identifies the pulse generator:

Dromos DR/DR-A



Dromos SR/SR-B



CAUTION

Because of the numerous available 3.2 mm configurations, e.g., the IS-1 and VS-1 standards, lead/pulse generator compatibility should be confirmed with the pulse generator and/or lead manufacturer prior to the implantation of a pacing system.

IS-1, wherever stated in this manual, refers to the international standard, whereby leads and generators from different manufacturers are assured a basic fit. [Reference ISO 5841-3:1992(E)].

CAUTION

Federal (U.S.A.) law restricts this device to sale by, or on the order of, a physician (or properly licensed practitioner).

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CAUTION

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1. Device Description

The BIOTRONIK Dromos DR and Dromos SR are rate adaptive multiprogrammable pulse generators. The Dromos DR is an atrial-based dual-chamber pacemaker and the Dromos SR is a single-chamber pacemaker suitable for either atrial or ventricular pacing therapy. The Dromos DR and Dromos SR have an accelerometer-based sensor and a rate-adaptive algorithm designed to automatically adjust the pacing rate to meet the patient's level of exertion.

2. Indications

Rate adaptive pacing with the Dromos DR and SR pulse generators is indicated for patients exhibiting chronotropic incompetence and who would benefit from increased pacing rates concurrent with physical activity. Please refer to Section 7, "Clinical Studies" for further details.

Generally accepted indications for long-term cardiac pacing include, but are not limited to: sick sinus syndrome (i.e., bradycardia-tachycardia syndrome, sinus arrest, sinus bradycardia), sino-atrial (SA) block, second- and third- degree AV block, and carotid sinus syndrome.

Patients whom demonstrate hemodynamic benefit through maintenance of AV synchrony should be considered for one of the dual-chamber or atrial pacing modes. Dual-chamber modes are specifically indicated for treatment of conduction disorders that require both restoration of rate and AV synchrony such as AV nodal disease, diminished cardiac output or congestive heart failure associated with conduction disturbances, and tachyarrhythmias that are suppressed by chronic pacing (see Appendix A of this manual).

3. Contraindications

Use of the Dromos pulse generators is contraindicated for the following patients:

- Unipolar pacing is contraindicated for patients with an implanted cardioverter-defibrillator (ICD) because it may cause unwanted delivery or inhibition of ICD therapy.
- Single-chamber atrial pacing is contraindicated for patients with impaired AV nodal conduction.
- Dual-chamber and single-chamber atrial pacing is contraindicated for patients with chronic refractory atrial tachyarrhythmias.

For a complete discussion of mode-specific contraindications, please refer to **Appendix A** of this manual.

4. Warnings

Certain therapeutic and diagnostic procedures may cause undetected damage to a pacemaker, resulting in malfunction or failure at a later time. Please note the following warnings and precautions, and refer to Section 15.5 for detailed information.

- Use of **therapeutic diathermy** equipment is to be avoided for pacemaker patients.
- **Transcutaneous electrical nerve stimulation (TENS)** may interfere with pacemaker function. If necessary, the following measures may reduce the possibility of interference:
 - Place the TENS electrodes as close to each other as possible.
 - Place the TENS electrodes as far from the pulse generator/lead system as possible.
 - Monitor cardiac activity during TENS use.

- **Magnetic resonance imaging** should be avoided as it has been shown to cause movement of the pulse generator within the subcutaneous pocket and may cause pain and injury to the patient and damage to the pulse generator.
- **Rate adaptive pacing** should be used with care in patients unable to tolerate increased pacing rates

5. Precautions

5.1 Storage

- Recommended storage temperature range is 5° to 55°C (41°-131°F). Exposure to temperatures outside this range may result in pacemaker malfunction. (see Section 10.1)
- Exposure to **low temperatures** (below 0°C) may cause a false elective replacement indication to be present. If this occurs, warm the device to room temperature and reset the ERI with magnet application. (see Section 10.1)

5.2 Pre-Implant

- **Do not drop.** If an unpackaged pulse generator is dropped onto a hard surface, return it to BIOTRONIK. (see Section 10.1)
- **If resterilization is necessary, use only ethylene oxide** at temperatures not exceeding 55° C (131° F), and aerate the packaged device until the concentration of ethylene oxide residue is below the level prescribed by applicable federal and/or state laws. Do not use steam sterilization (flash) or autoclave a pulse generator. (see Section 10.1)
- **Do not resterilize** a pulse generator or package that becomes contaminated by contact with body fluids. (see Section 10.1)
- Accessories packaged with the pulse generator are intended for one-time use. Do not resterilize them. (see Section 10.1)

5.3 Lead Connection

- **Lead/pulse generator compatibility** should be confirmed with the pulse generator and/or lead manufacturer prior to the implantation of a pacing system.

The Dromos DR and SR pacemakers are designed for use with **bipolar** leads having a 3.2 mm connector. The Dromos DR-A is designed for use with **unipolar** leads having a 5 mm Pin-Lock® PE connector. The Dromos SR-B is designed for use with an **unipolar** lead having a 6 mm Pin-Lock® PEC connector. (see Section 11)

- **Lead configuration** determines proper programming of the pulse generator. Pacing will not occur with a unipolar lead if the lead configuration is programmed to bipolar. (see Section 11)
- Failure to back-off the setscrew(s) prior to insertion of lead connector(s) may result in damage to the lead(s), and/or difficulty connecting lead(s).
- Do not overtighten the setscrew.
- Failure to properly insert the torque wrench into the perforation at an angle perpendicular to the connector receptacle may result in damage to the plug and its self-sealing properties. (DR/SR)
- If setscrews are not sealed with the provided sealing cap(s), pacemaker malfunction may occur. (DR-A, SR-B)

5.4 Electromagnetic Interference (EMI)

Patients should exercise reasonable caution in avoidance of devices which generate a strong electric or magnetic field. If EMI inhibits operation of a pulse generator or causes it to revert to asynchronous operation at the programmed pacing rate or at the magnet rate, moving away from the source or turning it off will allow the pulse generator to return to its normal mode of operation.

Some potential EMI sources include:

5.4.1 Hospital and Medical Environments

- **Electrosurgical cautery** could induce ventricular arrhythmias and/or fibrillation, or may cause asynchronous or inhibited pulse generator operation. If use of electrocautery is necessary, the current path (ground plate) should be kept as far away from the pulse generator and leads as possible. (see Section 15.6.7)
- **Lithotripsy** may damage the pulse generator. If lithotripsy must be used, do not focus the beam near the pulse generator. (see Section 15.6.6)
- **External defibrillation** may damage the pulse generator. Attempt to minimize current flowing through the pulse generator and lead system by following these precautions (see Section 15.6.1):
 1. Position defibrillation paddles as far from the pulse generator as possible. Attempt to minimize current flowing through the pulse generator and leads by positioning the defibrillation paddles perpendicular to the implanted pulse generator/lead system.
 2. Use the lowest energy output (watt seconds) as clinically acceptable.
 3. Confirm pacemaker function following any internal or external defibrillation.
- **High radiation sources** such as cobalt 60 or gamma radiation should not be directed at the pulse generator. If a patient requires radiation therapy in the vicinity of the pulse generator, place lead shielding over the device to prevent radiation damage. (see Section 15.6.3).

5.4.2 Home and Occupational Environments

- **High voltage power transmission lines** may generate enough EMI to interfere with pulse generator operation if approached too closely. (see Section 15.3)
- **Communication equipment** such as microwave transmitters, linear power amplifiers, or high-power amateur transmitters may generate enough EMI to interfere with pulse generator operation if approached too closely. (see Section 15.3)

- **Commercial electrical equipment** such as arc welders, induction furnaces, or resistance welders may generate enough EMI to interfere with pulse generator operation if approached too closely. (see Section 15.3)
- **Electric hand-tools and electric razors** (used directly over the skin of the pulse generator) have been reported to cause pacemaker disturbances. Home appliances which are in good working order and properly grounded do not usually produce enough EMI to interfere with pulse generator operation. (see Section 15.3.1).

5.4.3 Cellular Phones

Recent studies have indicated there may be a potential interaction between cellular phones and pacemaker operation. Potential effects may be due to either the radio frequency signal or the magnet within the phone and could include inhibition or asynchronous pacing when the phone is within close proximity (within 6 inches [15 centimeters]) to the pulse generator

Based on testing to date, effects resulting from an interaction between cellular phones and the implanted pacemakers have been temporary. Simply moving the phone away from the implanted device will return it to its previous state of operation. Because of the great variety of cellular phones and the wide variance in patient physiology, an absolute recommendation to cover all patients cannot be made.

Patients having an implanted pacemaker who operate a cellular phone should:

- Maintain a minimum separation of 6 inches (15 centimeters) between a hand-held personal cellular phone and the implanted device. Portable and mobile cellular phones generally transmit at higher power levels compared to hand held models. For phones transmitting above 3 watts, maintain a minimum separation of 12 inches (30 centimeters) between the antenna and the implanted device
- Patients should hold the phone to the ear opposite the side of the implanted device. Patients should not carry the phone

in a breast pocket or on a belt over or within 6 inches (15 centimeters) of the implanted device as some phones emit signals when they are turned ON but not in use (i.e., in the listen or standby mode). Store the phone in a location opposite the side of implant.

5.5 Disposal

Never incinerate a pulse generator. Be sure the pulse generator is explanted before a patient who has died is cremated. (see Section 14)

5.6 Programming

- Use only appropriate BIOTRONIK programmers equipped with appropriate software to program the Dromos pulse generators. Do not use programmers of other manufacturers.
- Computerized systems are subject to EMI or "noise". In the presence of such interference, telemetry communication is interrupted and prevents improper programming.
- Extreme programming changes should only be made after careful clinical assessment. Clinical judgement should be used when programming permanent pacing rates below 40 ppm or above 100 ppm. (see Section 8.2).
- Use of the OFF mode should be avoided in pacemaker dependent patients. The OFF mode can be transmitted as a temporary program only to permit evaluation of the patient's spontaneous rhythm. (see Section 8.1.11)

AC

6. Adverse Events

6.1 Observed Adverse Events

The Dromos DR Clinical Study involved 273 patients with a cumulative implant duration of 1418 months (mean implant duration 5.2 months). Eleven patients died during the course of the trial; none of the deaths were judged to be device-related. One Dromos DR pulse generator was explanted during the trial, secondary to infection.

Table 1 reports the adverse events on a per patient and a per patient-month basis. The last column gives the expected time between events; i.e., the reciprocal of the AE/patient-month rate.

Table 1.
Adverse Events Reported in > 1 Patient

All Dromos DR Patients (N=273), Number and % of Patients, Events/Patient Mo., and Pt-Mos. Between Events

Category	# pts (n-273)	% of patients	# of AEs	AE/pt-mo (n-1418)	Pt mos between AEs
Observations¹ (total)	79*	28.9%	86	0.0606	16
Atrial Loss of Sensing	10	3.7%	10	0.0071	142
Atrial Loss of Capture	8	2.9%	8	0.0056	177
Pacemaker Mediated Tachycardia	11	4.0%	12	0.0085	118
Premature AV Stimulation	4	1.5%	4	0.0028	355
Arrhythmias	34	12.5%	36	0.0254	39
Muscle/Diaphragmatic Stimulation	3	1.1%	3	0.0021	473
Unexplained Syncope	3	1.1%	3	0.0021	473
Complications² (total)	14*	5.1%	14	0.0099	101
Atrial Lead Dislodgement	6	2.2%	6	0.0042	236
Ventricular Lead Dislodgement	4	1.5%	4	0.0028	355

¹Observations are adverse events which correctable by non-invasive measures, e.g., reprogramming.

²Complications are adverse events requiring invasive measures to correct, e.g., surgical intervention.

*Not included in the Table are 6 observations and 4 complications each having only one occurrence.

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A

The **Dromos SR** Clinical Study involved 91 patients with a cumulative implant duration of 327 months (mean implant duration 3.6 months). Three patients died during the course of the trial; none of the deaths were judged to be device-related. During this clinical study, there were 3 ventricular lead dislodgements requiring invasive lead repositioning resulting in 0.0092 AE/pt-mo. and a mean pt-mo. between AEs of 109. There were 2 observations having only one occurrence each.

6.2 Potential Adverse Events

In addition to the adverse events reported in the clinical study, other possible adverse events may occur with this type of device based on implant experience including:

- Cardiac tamponade
- Cardiac perforation
- Air embolism
- Pocket erosion
- Infection
- Lead fracture/insulation damage
- Lead dislodgment
- Lead-related thrombosis
- Body rejection phenomena
- Muscle or nerve stimulation
- Elevated pacing thresholds
- Pocket hematoma
- Myopotential sensing
- Local tissue reaction/fibrotic tissue formation
- Pacemaker migration
- Pacemaker-mediated tachycardia (dual-chamber modes only)
- Undersensing of intrinsic signals

7. Clinical Studies

The Dromos DR and SR were studied in separate clinical studies summarized below:

7.1 Dromos DR

Primary Objectives: To evaluate the safety and effectiveness of the Dromos DR pulse generator and the utility of the DDDR pacing mode in patients with chronotropic incompetence (CI) in a crossover, double-blind trial. CI was defined as the inability to achieve a heart rate of **a)** 60% of their age predicted maximum (220-age), or **b)** 100 bpm.

Patients and Methods: A total of 273 patients were implanted with the Dromos DR pulse generator between July 21, 1995 and July 31, 1996, at 34 investigational centers (32 in the US, 1 France, and 1 Mexico). Mean patient age was 71 years with a range of 31 to 95, and 145 of 273 (53%) were male. Pre-implantation clinical symptomology was: bradycardia in 44% of the patients, dizziness in 31%, syncope in 25%, ECG indications were: Sick Sinus Syndrome in 46%, heart block in 40%, and atrial fibrillation/atrial flutter in 13% of the patients. The mean implant duration was 5.2 months (range = 0 to 16 months) with a total implant experience of 1418 months. At the one-month follow-up, 212 patients (91%) were programmed to a rate-adaptive mode according to the sensor parameter optimization procedure. Of the 63 patients completing a DDD exercise test (CAEP protocol) at one-month, 25 were found to be CI, and 21 completed the paired exercise testing at six-weeks. Patients performed the exercise tests, including metabolic measurements, in both the DDD and DDDR modes in randomized order.

Results:

Table 2.
Dromos DR Metabolic Exercise Testing at 6 Weeks

All chronotropically incompetent patients tested, n =21
Mean \pm SD and [95% confidence interval]

Endpoints	DDDR Mode	DDD Mode	Difference (CI)
Maximum VO ₂ (mL/kg/minute)	20.4 \pm 8.0	17.8 \pm 6.2	2.67* \pm 2.77 [1.5, 3.8]
VO ₂ @ AT (mL/kg/minute)	14.6 \pm 3.6	13.1 \pm 4.0	1.5* \pm 2.71 [0.33, 2.6]
Total exercise time (minutes)	9.2 \pm 3.0	8.2 \pm 3.3	0.92* \pm 1.08 [0.45, 1.4]
Exercise time to AT (minutes)	6.3 \pm 2.4	5.7 \pm 2.8	0.69* \pm 1.43 [0.04, 1.3]
Heart rate @AT (bpm)	113 \pm 16	84 \pm 16.5	29* \pm 18 [21,37]

95% confidence interval = mean difference \pm 1.96 SEM

*Difference statistically significant, p<0.05 by paired t-test

There were no pacemaker related deaths or unusual rates of observations or complications (see section 6, Adverse Events).

Conclusions: No unusual safety concerns were raised by the results of the clinical study. The accelerometer-based motion sensor provided the patients with appropriate rate-adaptation when programmed according to the sensor parameter optimization procedure. Additionally, the DDDR mode provided statistically significant improvement in metabolic measures during paired exercise testing of CI patients at 6 weeks.

7.2 Dromos SR

Primary Objective: To examine safety and evaluate the rate adaptive function of the Dromos SR pulse generator at one month follow-up.

Patients and Methods: A total of 91 patients were implanted with the Dromos SR pulse generator between November 8, 1995 and July 31, 1996 at 22 U.S. investigational centers. Mean patient age was 75 years with a range of 48 to 99, and 55 (60%)

were male. Pre-implantation clinical symptomology was: bradycardia in 57% of the patients, dizziness in 23%, syncope in 19%; ECG Indications were: atrial fibrillation/flutter in 68% and Sick Sinus Syndrome in 21% of the patients. The mean implant duration was 3.6 months (range=0 to 9 months) with a total implant experience of 327 months.

Ninety patients (99%) were implanted with the Dromos SR pulse generator attached to ventricular pacing leads and functioning in the ventricular mode. One patient (1%) was implanted with the Dromos SR pulse generator attached to an atrial lead and is functioning in the atrial mode. At the one-month follow-up, there were 73 patients (97%) programmed to the SSIR mode and 2 patients (3%) programmed to the SSI mode.

One month follow-up: Twenty patients performed a rate adaptive exercise test (CAEP protocol) at one-month. Six patients (30%) demonstrated 100% intrinsic rhythm due to atrial fibrillation with appropriate inhibition of sensor-driven pacing, seven patients (35%) demonstrated 100% sensor-driven pacing at or near the maximum sensor rate, and seven patients (35%) demonstrated a combination of intrinsic and sensor-driven pacing during the exercise testing.

For these 20 patients, maximum heart rate (bpm) mean \pm SD [95% CI] was 128 \pm 22 [119, 138], total exercise time (min) was 6.2 \pm 3.2 [4.8, 7.6], total METs was 4.2 \pm 1.9 [3.4, 5.0].

There were no pacemaker related deaths or unusual rates of observations or complications (see Section 6. Adverse Events).

8. Programmable Parameters

8.1 Pacing Modes

8.1.1 Rate Adaptive Modes

DDDR, DDIR, DVIR, VDDR, VVIR (SSIR), AAIR (SSIR), DOOR, VOOR (SOOR), AOOR (SOOR)

(Dual-chamber modes in Dromos DR/DR-A only)

Functioning of the rate adaptive modes is identical to that of the corresponding non-rate adaptive modes (refer to the following sections for details), except that the basic rate increases when physical activity is detected by the motion sensor. The non-rate adaptive modes of Dromos DR /SR are described below. In demand modes (DDDR, DDIR, DVIR, VDDR, VVIR, AAIR) it is possible that the atrial and/or ventricular refractory period can comprise a major portion of the basic interval at high sensor-modulated rates. This may limit the detection of spontaneous events or even exclude their recognition altogether. You will find further details in the "Programmable Parameters for Rate Adaptive Pacing" section of this manual.

8.1.2 DDD Mode

(Dromos DR/DR-A only)

Lower rate timing in the DDD mode starts with an atrial pace (A_p), an atrial sensed event (A_s) (Figure 1) or a ventricular sensed event outside of the AV delay (VES = "ventricular extrasystole") A-pace or A-sense starts the AV delay.

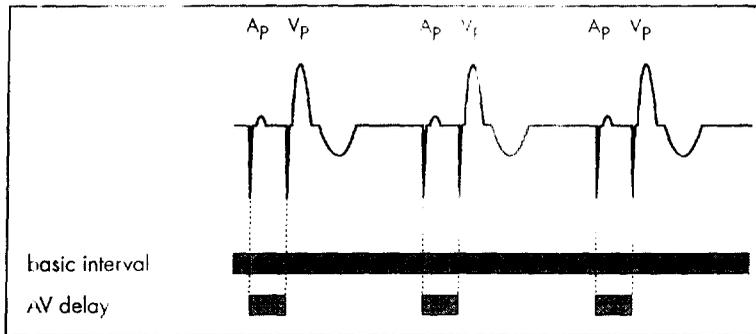


Figure 1. AV sequential pacing in absence of intrinsic activity in DDD mode.

A ventricular pace (V_p) will be emitted at the end of the AV delay if no ventricular sensed event (V_s) occurs by that time (Figure 2). The V-pace will be inhibited if a V-sense occurs within the AV delay (Figure 1); however, a V-sense within the safety AV delay results in a V pace at its end.

An A-sense, A-pace, or VES will start the atrial refractory period (ARP). A V-sense or V-pace will start the ventricular refractory period (VRP) and the interval corresponding to the upper tracking rate (UTR). Figure 3 summarizes the timing intervals started by atrial and ventricular pace and sense events

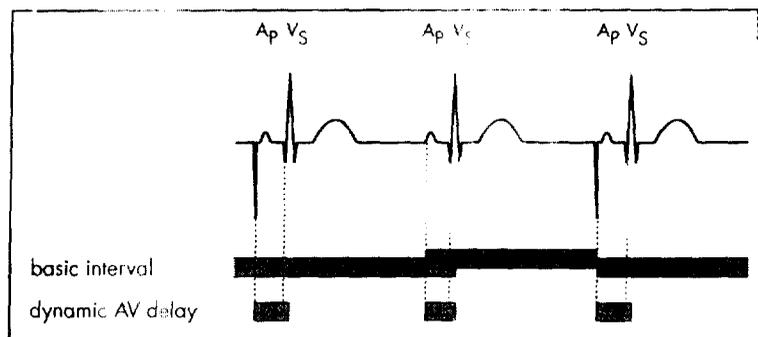


Figure 2. AV sequential pacing with intermittent intrinsic activity in DDD mode.

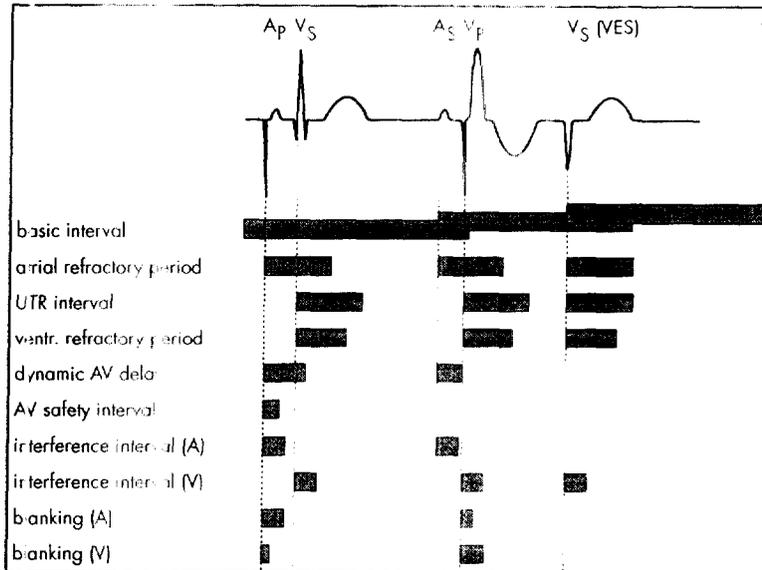


Figure 3. Timing intervals started by main timing events (DDD mode).

The graphically displayed information of Figure 3 is contained in the following table, which discriminates two kinds of ventricular pace and sense events, respectively: V-pace at the end of the AV delay (V_p) and V-pace at the end of the safety AV delay, referred to as ventricular safety pace, V_{sp} ; V-sense (V_s) within the AV delay and V-sense outside of the AV delay (referred to as "ventricular extrasystole", VES).

Timing intervals started by main timing events

Timing Interval	Event					
	A _P	A _S	V _P	V _{SP}	V _S	VES
lower rate interval (DDD)	x	x				x
lower rate interval (DDI)			x	x	x	x
atrial refractory period	x	x				x
atrial refractory period-ext.						x
UTR interval			x	x	x	x
ventricular refractory period			x	x	x	x
AV delay	x	x				
safety AV delay	x					
interference interval (A)	x	x				
interference interval (V)			x	x	x	x
blanking time (A)			x			
blanking time (V)	x					

NOTE:

In the pacing modes DDD(R), VDD(R), AAI(R), DDT, VDT, AAT, DOO(R) and AOO(R) lower rate timing starts with an atrial pace and/or sense event. In the pacing modes DDI(R), DVI(R), VVI(R), DDI/T and VOO(R), lower rate timing starts with a ventricular pace and/or sense event. In the DVT and DDI/T mode, lower rate timing starts with an atrial pace event and a ventricular sense event outside of the AV delay.

NOTE:

In the pacing modes DDI(R), DDI/T, VDD(R), and VDT, the atrial refractory period does not only start with an atrial pace and/or sense event, but will also be reset upon time-out of the VA-interval whether or not an atrial pulse is emitted.

8.1.3 DDDR Mode with Dual Demand (Automatic Mode Conversion)

(Dromos DR/DR-A only)

In the DDD(R) mode with dual demand OFF, atrial sensing within the refractory period does not retrigger the atrial refractory period interval. In the DDD(R) mode with dual demand ON, atrial sensing within the refractory period retriggers the atrial refractory period.

If the interval between successive P-waves becomes shorter than the atrial refractory period (i.e., during periods of tachycardia), the atrial refractory period will be re-started continuously. Thus the period is extended through the entire basic interval. At the end of the basic interval an atrial pulse is emitted asynchronously and the AV delay started. As a result, the pacemaker acts as if it were placed in the DVI mode and ventricular pacing triggered by P-wave tracking is prevented.

Dual demand differs in the DDD mode from the DDD(R) mode in that pacing occurs at the lower rate (DDD), whereas in the DDD(R) mode pacing occurs at the sensor indicated rate.

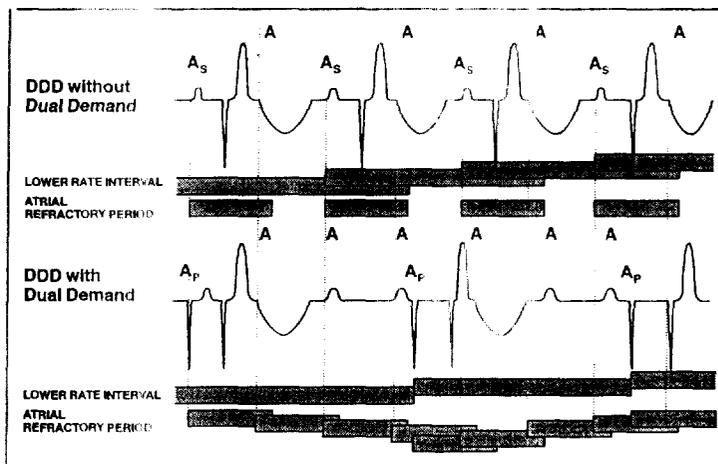


Figure 4. DDD Mode *without* (upper panel) and *with* Dual Demand Modality (lower panel).

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Referring to Figure 4, "A_s," "A_p," and "A" indicate atrial sensed events, unused atrial sensed events (inside refractory), and atrial paced events, respectively. In the top diagram, every other P-wave triggers ventricular pacing during an atrial arrhythmia. In the lower diagram, P-waves falling within the atrial refractory period (ARP) retrigger the ARP without resetting the lower rate timer during the atrial arrhythmia.

8.1.4 DDI Mode

(Dromos DR/DR-A only)

The DDI mode provides atrial and ventricular sensing and pacing but, in contrast to the DDD mode, no P-wave triggered ventricular stimulation. The timing of the lower rate interval starts with a ventricular (sense or pace) event. The lower rate interval comprises the VA-interval and the AV delay. In the absence of atrial and ventricular sense events, an A-pace will be emitted at the end of the VA-interval, and a V-pace at the end of the AV delay.

If an atrial sense event occurs within the VA-interval, no atrial pulse will be emitted at the end of the VA-interval and the AV delay will start upon expiration of the VA-interval. In the absence of a ventricular sense event, a ventricular pulse will be emitted at the end of the AV delay.

In the DDI mode as well as in certain other pacing modes (DDIc, DDI/T, VDD, VDDc, and VDT), the atrial refractory period does not only start with an atrial (sense or pace) event but will also be reset when the VA-interval has elapsed, even though no atrial (sense or pace) event occurs at the end of the VA-interval.

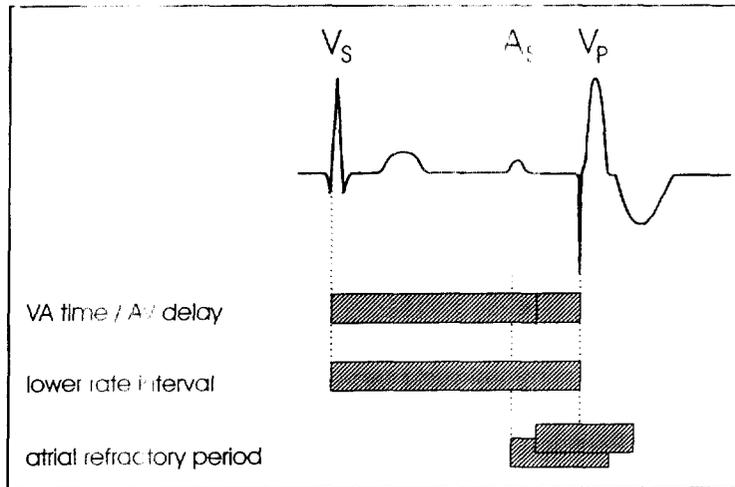


Figure 5. Atrial pulse inhibition by A-sense occurring within the VA-time. Timeout of VA-time resets ARP (DDI standard program).

A ventricular sense event during the VA time inhibits atrial and ventricular pulse emission and resets the lower rate timer. A ventricular sense event within the AV delay but outside of the safety AV delay, inhibits V-pace and resets the lower rate timer.

8.1.5 DVI Mode

(Dromos DR DR-A only)

The DVI mode does not provide atrial sensing. Like the DDI mode, the timing of the lower rate interval (LRI) starts with a ventricular (sense or pace) event. The LRI comprises the time from the ventricular event to the atrial pace (VA-interval) and the AV delay. In the absence of a V-sense, an atrial pulse will be emitted at the end of the VA-interval, followed by a ventricular pulse at the end of the AV delay. A ventricular sense event during the VA-interval inhibits atrial and ventricular pulse emission and resets the lower rate timer. A ventricular sense event within the safety AV delay causes emission of a ventricular pulse at its end. A ventricular sense event within the AV delay, but outside of the safety AV delay, inhibits V-pace and resets the lower rate timer.

8.1.6 VDD Mode

(Dromos DR/DR-A only)

The VDD mode corresponds to the DDD mode with the exception that it does not provide atrial pacing.

The lower rate interval is reset by an atrial sense event or, if absent, it starts upon expiration of the VA-interval. The AV delay and the ARP are also started together with the lower rate interval. A ventricular sense event within the AV delay will inhibit V-pace. A ventricular sense event outside of the AV delay will reset the lower interval and start the ARP but not the AV delay. For prevention of pacemaker mediated tachycardias (PMT), the ARP will be reset by a ventricular pulse which was not triggered by an atrial sense event.

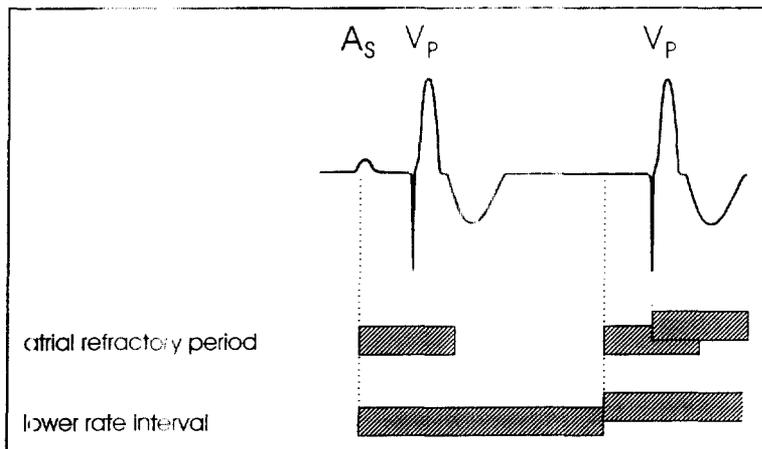


Figure 6. Restart of ARP with V-pace not triggered by A-sense for PMT prevention. The VDD mode, instead of the DDD mode, is indicated if atrial pacing is not desired, as may be the case when the phrenic nerve is stimulated.

AK

8.1.7 VDD(R) Mode with Dual Demand (Automatic Mode Conversion)

(Dromos DR/DR-A only)

The Dual Demand function in VDD(R) mode causes an automatic conversion to VVI(R) mode during atrial tachycardia. In the VDD(R) mode with Dual Demand OFF, atrial sensing within the refractory period does not retrigger the atrial refractory period. In the VDD(R) mode with Dual Demand ON, atrial sensing within the refractory period restarts the atrial refractory period.

If the interval between successive P-waves becomes shorter than the atrial refractory period, the atrial refractory period will be restarted continually. Thus, the pacemaker remains refractory in the atrium for the entire basic interval. At the end of the basic interval, the AV delay is started. As a result, the pacemaker acts as if it were set to the VVI(R) mode for the duration of atrial tachycardia. Atrial triggered ventricular pacing at high rates is prevented.

8.1.8 AAI and VVI Modes

(SSI in Dromos SR/SR-B)

The pacing modes AAI and VVI provide atrial and ventricular demand pacing. The lower rate timer is started by a sense or pace event. A sense event outside of the refractory period inhibits pacing and resets the lower rate timer; in the absence of a sense event, a pacemaker pulse will be emitted at the end of the lower rate interval.

8.1.9 AOO, VOO, and DOO Modes

(DOO in Dromos DR/DR-A only)

In these modes atrial, ventricular and AV sequential pulses, respectively, are emitted asynchronously. They primarily serve diagnostic purposes during follow-up. Conversion to asynchronous pacing is occasionally considered when inappropriate pulse inhibition cannot be corrected by reprogramming, as may be encountered in leads having an insulation defect. When program-

ming to the VOO or DOO mode, the risks associated with asynchronous ventricular pacing should be considered. The DOO mode may occasionally be used for the acute therapy of certain supraventricular reentry tachycardias.

8.1.10 VDI Mode

(Dromos DR/DR-A only)

The VDI mode corresponds to the VVI mode, with the additional function of providing atrial sensing. The purpose of the VDI mode is to permit the use of the marker function with the IEGM for the atrial channel. For example, to measure the retrograde conduction time.

The VA conduction time between a ventricular pace or sense event (with marker), and the signal indicating the atrial sense event, can be measured directly on the display or printout of the programmer (e.g. PMS 1000; IEGM function) or on an ECG strip chart recorder (IEGM/marker output function).

Magnet operation must be synchronous to enable transmission of atrial sense markers.

8.1.11 OFF Mode

In this mode, pulses are not generated.

WARNING

Use of the OFF mode with pacemaker dependent patients is contraindicated, due to the lack of pacemaker output.

The OFF mode can be transmitted as a temporary program only. It serves for the evaluation of the patient's spontaneous rhythm.

8.1.12 Pacing Modes with Triggered Response

(Dual-chamber modes - Dromos DR/DR-A only)

Pacing modes with triggered response correspond to their respective demand pacing modes, except that a sensed event will not inhibit but will rather trigger a pacing pulse, simultaneously with the sensed event, into the same chamber where sensing has occurred. The demand and triggered pacing modes corresponding to each other are:

Demand: DDD, DDI, DVI, VDD, AAI (SSI), VVI (SSI)
Triggered: DDT, DDI/T, DVT, VDT, AAT (SST), VVT (SST)

As compared to the demand pacing modes DDD, DVI and DDI, the corresponding triggered pacing modes DDT, DVT and DDI/T limit the AV delay to a maximum of 150 ms and do not provide a safety AV delay. The safety AV delay is meant to prevent an inappropriate inhibition of the ventricular pulse if the atrial pulse emission is sensed by the ventricular channel; such inhibition cannot occur in a mode providing triggered pacing.

Lower rate timing in the pacing modes DDI/T and DVT differs from that of the corresponding demand pacing modes DDI and DVI with respect to ventricular sense events occurring during the AV delay. In the demand pacing modes, they reset the lower rate interval, while in the triggered pacing modes they do not.

Pacing modes with triggered response may be indicated in the presence of interference signals to prevent inappropriate pulse inhibition. They may also have diagnostic application for ECG identification of sense events as an alternative to marker signals. In the DDT mode, for example, pacemaker pulses can be used to serve as atrial and ventricular sense event markers for evaluation of the pacing system's sensing performance. This is particularly important during exercise when it is impossible or impractical to keep the programming head appropriately positioned over the implanted pacemaker to record marker signals.

Triggered pacing may also be used for hemodynamic as well as electrophysiologic studies and for termination of tachycardias by

noninvasive triggering of pacemaker pulses with chest wall stimuli generated by an external pulse generator.

CAUTION

When programmed to triggered modes, pacing rates up to the programmed upper limit may occur in the presence of either muscle or external interference.

CAUTION

While the triggered modes (DDT, DVT, DDI/T, VDT, VVT, and AAT) can be programmed permanently, the use of these modes is intended as a temporary setting in situations where maintaining the programming head in place would be impossible or impractical (i.e., during exercise testing or extended Holter monitoring) or as a short term solution to pacemaker inhibition by extracardiac interference. To avoid the potential for early battery depletion, it is important that the triggered modes are not used for long term therapy, and that the pacemaker is returned to a non-triggered permanent program upon completion of the intended diagnostic function or resolution of the interference issue.

8.2 Summary of Programmable Functions

NOTE:

The programmability of pacing modes, parameters and parameter values is determined by the software used for programming/interrogating the pacemaker

8.2.1 Lower Rate

Programmable values

Dromos DR/DR-A: 30...(1)...88...(2)...122...(3)...140 ppm

Dromos SR/SR-B: 30...(1)...88...(2)...122...(3)...140...(5)...180 ppm

1

The lower rate is the pacing rate in the absence of a spontaneous rhythm

CAUTION

Lower rates of less than 40 ppm should only be used to assess sensing and a patient's intrinsic rate. Permanent programming of these rates is not recommended.

8.2.2 Hysteresis

Programmable values

OFF, -6, -12, 18 bpm

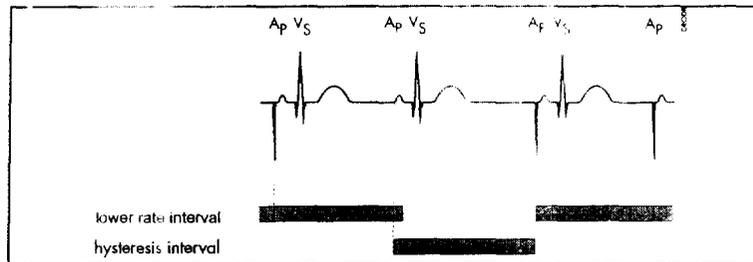


Figure 7. DDD mode in Dromos DR/DR-A with hysteresis and lower rate intervals

Hysteresis can be programmed OFF or to the above listed values. The hysteresis rate is based on the lower rate and the value of the programmable parameter. The resulting hysteresis rate is always less than the lower rate. A conflict symbol (>>) will appear and transmission will be prohibited for hysteresis rates which are less than 30 bpm. The ability to decrease the effective lower rate through hysteresis is intended to preserve a spontaneous rhythm. The pacemaker operates by waiting for a sensed event throughout the effective lower rate interval (hysteresis interval). If no sensed event occurs, a pacing pulse is emitted following the hysteresis interval.

Hysteresis is not available in the modes DDIR, DVIR, VVIR, and SSIR (Dromos SR).

8.2.3 Pulse Amplitude

Programmable values

0 1...(0.1)...4 8...(1.2)...9.6 V

The selected pulse amplitude determines the electrical potential applied to the heart during the pacing pulse. The pulse amplitude is independently programmable for the atrial and ventricular channel of the pacemaker (dual-chamber only). In the rate responsive modes, the amplitude is limited to a maximum value of 4.8 V.

NOTE:

As a result of the Pulse Amplitude Control (PAC) System, the pulse amplitude remains constant throughout the service life of the pulse generator. The stimulation safety margin is therefore not reduced by a decrease in the pulse generator's battery voltage.

CAUTION

Programming of pulse amplitudes, higher than 4.8 V, in combination with long pulse widths and/or high pacing rates, even with batteries in the BOS state, can lead to premature activation of the replacement indicator.

If a pulse amplitude of 7.2 V or higher is programmed and high pacing rates are reached, output amplitudes may differ from programmed values.

CAUTION

When decreasing programmed output (pulse amplitude and/or pulse width), the pacing threshold must **first** be accurately assessed to provide the prescribed safety margin.

8.2.4 Pulse Width

Programmable values

0.25, 0.50, 0.75, 1.0 ms

The selected pulse width determines the duration for which the programmed pulse amplitude will be applied to the heart. The pulse width is independently programmable for the atrial and ventricular channels of the pacemaker (dual-chamber only). Pulse width remains constant throughout the service life of the pulse generator.

8.2.5 Sensitivity

Programmable values

Atrial Sensitivity:

Dromos DR/DR-A 0.5...(0.5)...7.5 mV

Dromos SR/SR-B 0.4...(0.4)...6.0 mV

Ventricular Sensitivity:

0.5...(0.5)...7.5 mV

The parameter "sensitivity" is used to set the pacemaker's recognition threshold for intracardiac signals. The lower the set value, the higher the sensitivity. If bipolar leads are implanted and programming to high sensitivity is required to avoid undersensing, programming to bipolar sensing in combination with unipolar or bipolar pacing should be considered for improvement of the "signal-to-noise" ratio. This is to prevent sensing of interference signals, e.g. myopotentials.

An intracardiac signal of sufficient amplitude outside of the refractory period inhibits or triggers stimulation depending on the programmed mode. The filter characteristics of the sensing circuits have been specifically designed for optimum recognition of intracardiac signals and suppression of interference.

If intracardiac signals are of low amplitude, a change to a higher sensitivity (lower value) may be indicated. Conversely, if the sensing amplifier is responding to extraneous signals, such as artifacts or interference, a change to a lower sensitivity (higher value) may resolve the difficulty. In dual-chamber sensing

modes, the sensitivity values for the atrial and ventricular channels are independently programmable

8.2.6 Refractory Period

Programmable values

Atrial refractory period:

Dromos DR/DR-A	200...(25)...775 ms
Dromos SR/SR-B	250, 300, 350, 400 ms

Ventricular refractory period:

Dromos DR/DR-A	250, 300, 350, 400 ms
Dromos SR/SR-B	250, 300, 350, 400 ms

Immediately upon sensing or pacing, the pacemaker starts a refractory period in the channel where sensing/pacing has occurred. During the refractory period, intracardiac signals are ignored. This prevents the pacemaker from responding to the terminal portion of the depolarization signal or the repolarization signal (T-wave) that might otherwise result in inappropriate inhibition or triggering.

If the pacemaker is programmed to a dual-chamber sensing mode (Dromos DR/DR-A), the refractory periods are independently programmable for each sensing channel. The pulse generator's ventricular refractory period is always initiated by a sensed or paced ventricular event. The atrial refractory period is always initiated by a sensed or paced atrial event or a sensed ventricular event outside of the AV delay (e.g., PVC).

Under certain circumstances [i.e., dual demand (DDD(R), VDD(R))] additional sensed events will retrigger the atrial refractory period. Refer to the appropriate section of the manual for details.

CAUTION

Use of short pacing intervals (high pacing rates) with long atrial and/or ventricular refractory periods may result in intermittent asynchronous pacing and, therefore, may be contraindicated in some patients.

8.2.7 Atrial Refractory Period Extension (ARPE)

(Dromos DR/DR-A only)

Programmable values

0...(50)...350 ms

The ARPE applies to the pacing modes DDD, VDD, DDT and VDT. To prevent the initiation of a PMT by a ventricular depolarization not preceded by an atrial depolarization, the ARP will be extended by the ARPE if the ARP:

- was started by a ventricular sense event outside of the AV delay (e.g., PVC) in the pacing modes DDD, DDT, VDD and VDT, or
- was reset by a ventricular pulse not triggered by an atrial sense event in the pacing modes VDD and VDT.

In these instances, the ARP will usually be long enough to prevent sensing of the retrograde P-wave. Programming to an ARPE other than 0 ms may rarely be required but could provide additional protection if the ARP is particularly short or the retrograde conduction time exceptionally long.

8.2.8 AV Delay/Dynamic AV Delay

(Dromos DR/DR-A only)

Programmable values

AV Delay: 15, 50, 75, 100, 120...(10)...200, 225, 250, 300 ms

Dynamic AV Delay: Low, Medium, High, Individual, Fixed

The AV delay defines the interval between an atrial paced or sensed event and the ventricular pacing pulse. If the pacemaker is programmed to a dual-chamber sensing mode, an intrinsic ventricular event falling within the AV delay will inhibit the ventricular pacing pulse. If not contraindicated, a longer AV delay can be selected to increase the probability of ventricular output pulse inhibition. Short AV delays are available for testing pur-

poses or if ventricular pre-excitation is desired (i.e., hemodynamic considerations).

Dynamic AV delay is an additional option where the AV delay is varied depending on the spontaneous atrial rate when programmed to non-rate adaptive modes, or depending on the sensor driven rate and/or intrinsic rate when programmed to rate adaptive modes. Dynamic AV delay provides independent selection of AV delays from five rate ranges at pre-set AV delay values.

Dynamic AV delay is programmable within the following atrial rate ranges at the values specified:

Rate Ranges	LOW	MED	HIGH
below 70 bpm	170 ms	160 ms	150 ms
70 - 90 bpm	160 ms	140 ms	120 ms
91 - 110 bpm	150 ms	120 ms	100 ms
111 - 130 bpm	130 ms	100 ms	75 ms
above 130 bpm	120 ms	75 ms	50 ms

In addition to selecting the pre-set values (low, medium, high) within the Dynamic AV Delay window, the dynamic AV delays may be programmed **individually** or a **fixed** AV delay may be programmed.

The dynamic AV delay is intended to mimic the physiologic, catecholamine-induced shortening of the AV delay with increasing rate. It also serves for automatic prevention/termination of "circus movement" pacemaker mediated tachycardia and for prevention of reentrant supraventricular tachycardia (see page 49, Automatic PMT Prevention/Termination).

8.2.9 Ventricular Blanking Period

(Dromos DR/DR-A only)

Programmable values

12, 16, 24, 32, 40, 48, 56, 72 ms

123

The ventricular blanking time is the period after an atrial pacing pulse during which ventricular sensing is deactivated. It is intended to prevent ventricular sensing of the atrial pacing pulse ("crosstalk").

The blanking time shall be as short as possible so as to provide ventricular sensing when a ventricular depolarization could occur. However, the blanking time must not be so short that the atrial pacing pulse is detected as a ventricular sensed event, as may be the case when the atrial pulse amplitude and pulse width are high and/or the ventricular sensitivity is high (i.e., if the selected sensitivity value is low) and/or in unipolar polarity.

Crosstalk may be encountered if a shorter blanking time, unipolar ventricular sensing, a higher ventricular sensitivity (lower value) and/or a high atrial pulse amplitude and pulse width are programmed.

8.2.10 Safety AV Delay

(Dromos DR/DR-A only)

Programmable values

100, 125, 150 ms

The safety AV delay applies to the pacing modes DDD(R), DVI(R) and DDI(R).

To prevent ventricular pulse inhibition in the presence of crosstalk, a ventricular pulse will be emitted at the end of the safety AV delay. When pacing is AV sequential at the programmed safety AV delay, the presence of crosstalk should be considered and appropriate reprogramming performed (prolong the ventricular blanking time, lower ventricular sensitivity, bipolar configuration, and/or lower atrial pulse energy)

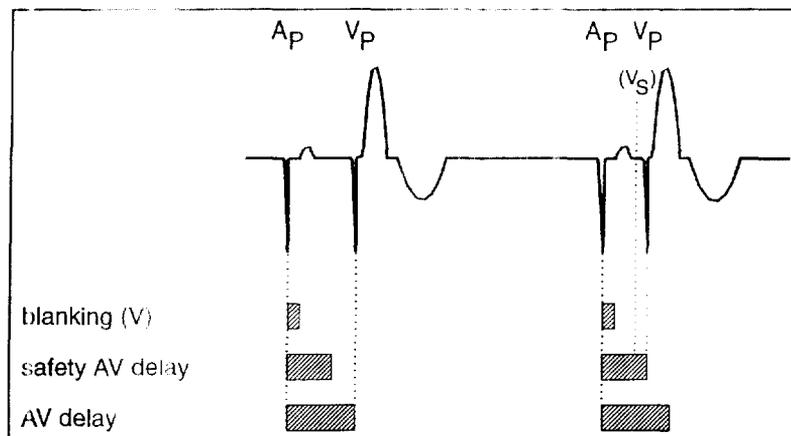


Figure 8. Ventricular blanking time and safety AV delay (Dromos DR/DR-A)

8.2.11 Upper Rate and UTR Response

Programmable values

Upper rate : 100, 110, 120, 130, 140, 160, 185 ppm
 UTR response*: 2:1, WRL (Automatic Selection)

*Dromos DR/DR-A only

The upper rate is programmable for the dual-chamber sensing modes [DDD(R), VDD(R)], and for all triggered modes (single- and dual-chamber). The ventricular pacing rate will never exceed the programmed upper rate regardless of the patient's atrial rate. The UTR response will automatically toggle between 2:1 and WRL depending on the relative programmed values for upper rate and atrial refractory period.

If the UTR is less than the maximum sensed atrial rate, defined by the atrial refractory period ($60,000 \div \text{ARP}$), the WRL response is utilized. Atrial rates exceeding the selected upper rate will result in a Wenckebach-type pacing pattern. This is accomplished by progressively lengthening the AV delay to keep the ventricular pacing rate at the upper rate. Lengthening of the AV interval is interrupted as soon as: 1) a P-wave falls within the atrial blanking period and is not de-

tected; or 2) a succeeding P-wave is detected before the end of the AV delay previously started. In the second case, the corresponding ventricular pacing pulse is suppressed. If the atrial rate is just above the upper rate, a low degree (i.e. 6:5) block results. Higher atrial rates result in higher degrees of AV block until the intrinsic atrial cycle length violates the programmed atrial refractory period causing a 2:1 or greater block.

The 2:1 response is utilized when the rate defined by the atrial refractory period is less than the upper rate and dual demand is OFF. In such a case, the maximum pacing rate is regulated by the inability to respond to P-waves falling within the atrial refractory period.

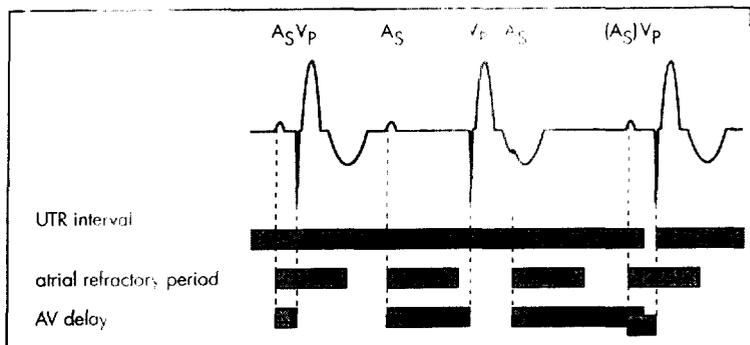


Figure 9. Wenckebach-type pacing pattern (Dromos DR/DR-A).

8.2.12 Lead Polarity

Programmable values (Dromos DR)

- A · sense: unipolar, bipolar
- A · pace: unipolar, bipolar
- V · sense: unipolar, bipolar
- V · pace: unipolar, bipolar

The programmed lead polarity determines whether the pulse generator senses or paces in a unipolar or bipolar configuration. Lead polarity can be programmed separately for sensing and pacing in both chambers. There are nine (9) possible configurations available in the Dromos DR:

100

Atr. Sense	Atr. Pace	Ventr. Sense	Ventr. Pace
UNIP	UNIP	UNIP	UNIP
UNIP	UNIP	BIPL	UNIP
BIPL	UNIP	UNIP	UNIP
BIPL	UNIP	BIPL	UNIP
BIPL	UNIP	UNIP	BIPL
BIPL	UNIP	BIPL	BIPL
UNIP	BIPL	BIPL	UNIP
BIPL	BIPL	BIPL	UNIP
BIPL	BIPL	BIPL	BIPL

NOTE:

If unipolar sensing is used in one chamber, unipolar pacing is required in the opposite chamber

Programmable values (Dromos SR)

Sense: unipolar, bipolar
 Pace: unipolar, bipolar

If a bipolar lead is connected to the pacemaker, unipolar or bipolar configuration can be independently programmed for pacing and sensing

As compared to bipolar pacing, the unipolar pacing pulse has the advantage of being clearly identifiable on the ECG and having a somewhat lower energy consumption. Unipolar pacing occasionally results in muscle stimulation in the pacemaker pocket or diaphragm

Bipolar sensing offers a better "signal-to-noise" ratio because of the lower susceptibility to interference signals like skeletal myopotentials or EMI, and, therefore, permits programming of higher sensitivities (lower values).

WARNING

The Dromos DR and SR can be operated with either unipolar or bipolar IS-1 leads. If the pacing or sensing function is to be programmed bipolar for either chamber, it must be verified that **bipolar leads** have been implanted in the respective chamber. If either of the leads is unipolar, unipolar sensing and pacing functions must be programmed in that chamber. Failure to do this results in an entrance and/or exit block for the chamber(s) with unipolar lead(s).

In addition, if the lead polarity setting within the Patient Data Memory has been set to **bipolar**, the polarity of the corresponding implanted lead(s) must be confirmed to be **bipolar**.

Programmable values (*Dromos DR-A and Dromos SR-B*)

Sense/Pace unipolar

The Dromos DR-A and Dromos SR-B have been designed for use with atrial or ventricular UNIPOLAR lead(s) only.

Upon interrogation of the Dromos DR-A/SR-B by the PMS 1000, the Dromos DR-A/SR-B will be identified as "Dromos DR-U" or "Dromos SR-U" to designate a unipolar header. The lead polarity sense/pace are restricted to unipolar and cannot be programmed otherwise

8.3 Programmable Parameters for Rate Adaptive Pacing

8.3.1 Rate Adaptation

The pacemaker is equipped with an accelerometer located on the hybrid circuit of the pacemaker. This sensor produces an electric signal during physical activity of the patient. If a rate adaptive mode is programmed, then the sensor signal controls the stimulation rate. Sensing and inhibition remains in effect during sensor controlled operation. In case of high pacing rates,

however, the refractory periods may cover a majority of the lower rate interval, resulting in asynchronous operation.

The following modes can be chosen from the mode selection list of the programmer (dual-chamber modes available in Dromos DR/DR-A only):

DDDR, DDIR, DVIR, VDDR, DOOR, VVIR (SSIR),
VOOR (SOOR), AAIR (SSIR), AOOD (SOOR)

8.3.2 Sensor Gain

Programmable values

1, 1.3, 1.6, 2, 3, 4, 5, 6, 7, 8, 10, 11, 12, 14, 16, 20, 24, 28, 32, 40

The sensor gain defines the slope of the linear function between exertion and pacing rate. It designates a factor by which the electric signal of the sensor is amplified prior to the signal processing stages. The programmable amplification permits adaptation of the individually programmed sensor gain to the desired rate response. The optimum setting is achieved when the desired maximum pacing rate during exertion is reached during maximum exercise levels. The rate increase, rate decrease and maximum sensor rate settings must be checked for their suitability with respect to the individual patient before adjusting the sensor gain.

If the sensor-driven rate is not sufficient at high levels of exertion the sensor gain setting should be increased. The sensor gain should be reduced if high pacing rates are obtained at low levels of exertion.

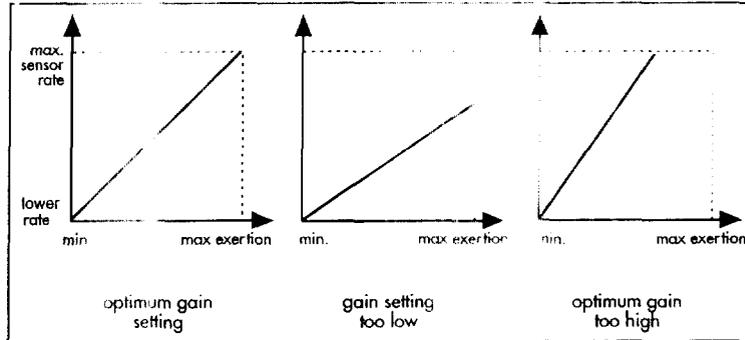


Figure 10 Influence of sensor gain on the rate response

8.3.3 Sensor Threshold

Programmable values

LOW, MEAN HIGH

The effects of rate adaptation are limited to sensor signals exceeding the programmable sensor threshold. Sensor signals below this threshold do not affect rate response (Figure 11). The programmable sensor threshold ensures that a stable rate at rest can be achieved by ignoring sensor signals of low amplitude that are not related to exertion.

If the pacing rate at rest is unstable, or tends to stay above the lower rate without activity, the sensor threshold should be increased. The sensor threshold should be reduced if a sufficient rate increase is not observed at a given level of exertion.

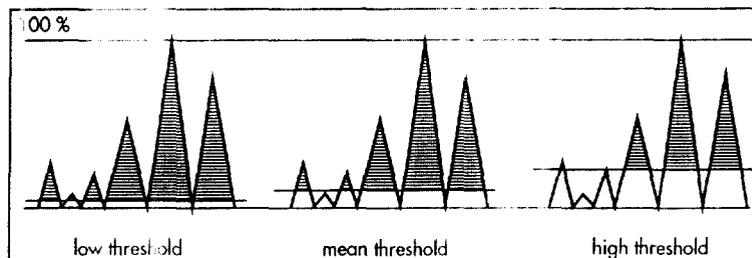


Figure 11 Effect of sensor threshold

8.3.4 Rate Increase

Programmable values

SLOW, MEAN, FAST, VERY FAST

The rate increase parameter determines the maximum rate of change in the pacing rate if the sensor signal indicates increasing exertion (Figure 12). In the modes DDDR, VDDR, DOOR, VVIR (SSIR), VOOR (SOOR), AAIR (SSIR) and AOOD (SOOR), the rate increase setting "mean" results in a 2 ppm per second increase in pacing rate. For example, it takes 45 seconds to change from a pacing rate of 60 ppm to 150 ppm.

Rate Increase Setting	Increase in Rate (ppm/s)	Time to Increase Rate (seconds)
Slow	1	90
Mean	2	45
Fast	4	23
Very Fast	8	11

In the modes DDIR and DVIR, the rate increase is slightly slower than indicated here (depending on the programmed AV interval). The programmed rate increase setting applies only to the increase in pacing rate during sensor driven operation and does not affect the pacing rate during atrial triggered ventricular pacing.

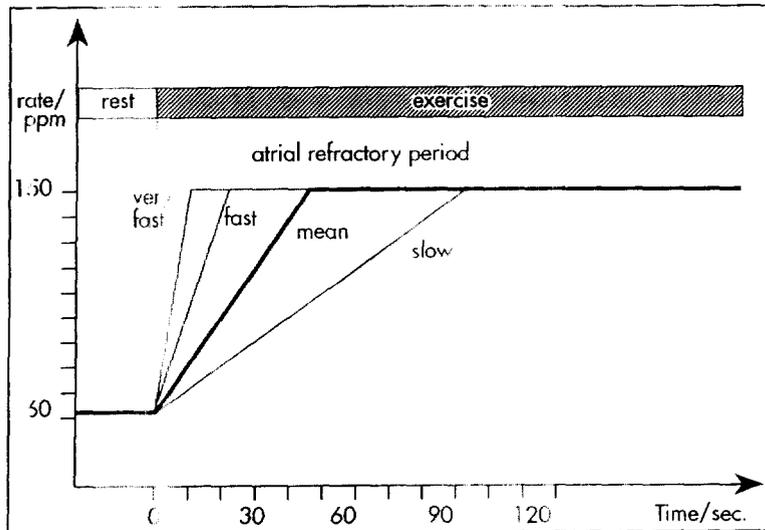


Figure 12. Rate increase during exercise

8.3.5 Maximum Sensor Rate

Programmable values

Dromos DR:	100, 125, 150, 170 ppm
Dromos SR:	100, 125, 145, 165 ppm

Regardless of the sensor signal strength the pacing rate during sensor-driven operation will never exceed the programmed maximum sensor rate (Figure 13). The maximum sensor rate only limits the pacing rate during sensor-driven operation and does not affect atrial triggered ventricular pacing. The maximum sensor rate must be less than or equal to the programmed UTR.

NOTE:

In the DDIR and DVIR modes, lower maximum sensor rates result, depending on the selected AV interval. The actual values are displayed on the programmer screen. Short AV intervals result in high maximum sensor rates.

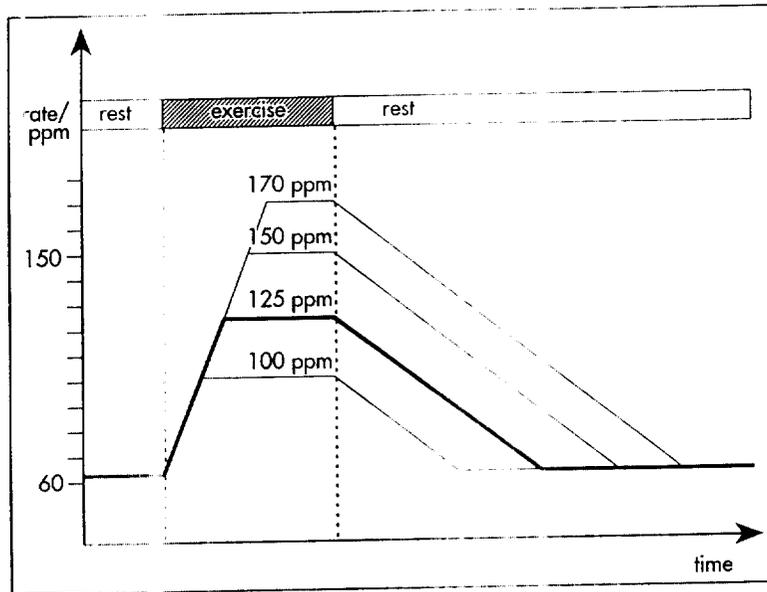


Figure 13. Maximum sensor rate

8.3.6 Rate Decrease

Programmable values

VERY SLOW, SLOW, MEAN, FAST

The rate decrease parameter determines the maximum rate of change in the pacing rate, if the sensor signal indicates decreasing exertion (Figure 14). In the modes DDDR, VDDR, DOOR, VVIR (SSIR), VOOR (SOOR), AAIR (SSIR), and AOOR (SOOR), the rate decrease setting "mean" results in a 0.4 ppm per second decrease in pacing rate. For example, it takes 225 seconds to change from 150 ppm to 60 ppm.

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Rate Decrease Setting	Decrease in Rate (ppm/s)	Time to Decrease Rate (seconds)
Very Slow	0.1	900
Slow	0.2	450
Mean	0.4	225
Fast	0.8	112

In the modes DDIR and DVIR, the rate decrease is slightly slower than indicated here (partly depending on the programmed AV interval).

The programmed rate decrease setting applies only to the decrease in pacing rate during sensor-driven operation and does not affect the pacing rate during atrial triggered ventricular pacing.

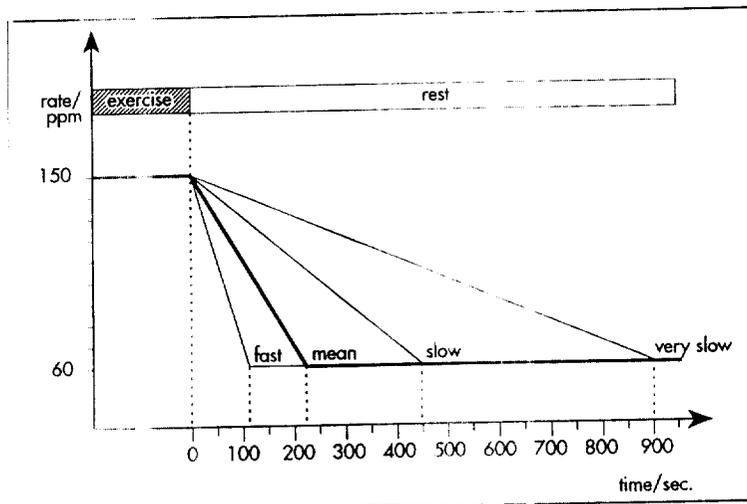


Figure 14. Rate decrease after exercise

9. Other Functions/Features

9.1 “Safe Program” Settings

Activating the pre-set values for the “Safe Program” is a quick and convenient way to provide VVI/SSI pacing at a high output setting in urgent situations. Listed below are the Dromos DR and Dromos SR pacemaker “Safe Program” settings.

	Dromos DR	Dromos SR
Mode	VVI	SSI
Pacing Rate	70 ppm	70 ppm
Amplitude	4.8 V	4.8 V
Pulse Width	ms	1.0 ms
Sensitivity	2.5 mV	2.5 mV ventr. 2.0 mV atrial
Pacing Polarity	Unipolar	Unipolar
Ventricular Refractory Period	300 ms	300 ms
Single Chamber Hysteresis	OFF	OFF

9.2 Magnet Effect

Programmable values

Asynchronous, Synchronous

When programmed to asynchronous operation, closing the reed switch (magnet application) results in asynchronous pacing which is dependent on the programmed mode:

- In the DDD(R), DDT, DOO(R), VDD(R), VDT, AAI(R), AAT, AOO(R), VVI(R), VVT and VOO(R) modes, the pacemaker paces at 90 ppm for 10 cycles. Thereafter, if the magnet remains over the pacemaker, pacing will be at the programmed lower rate and rate adaption is deactivated.

- In the DDI(R), DDI/T, DVI(R) and DVT modes (R-synchronous) the pacemaker paces asynchronously at 90 ppm as long as the magnet is over the pacemaker.

Upon magnet removal, the current basic interval is completed before the pacemaker reverts to its original operating mode.

If the magnet effect is set to asynchronous, the AV delay is reduced to 100 ms (or the programmed AV delay, whichever is shorter). Shortening of the AV delay to 100 ms during asynchronous AV sequential stimulation is provided to avoid ventricular fusion beats in the presence of intact AV conduction. This allows efficient diagnosis of ventricular capture or failure to capture.

If the magnet effect is programmed to synchronous operation (temporary mode only), closing the reed switch (magnet application) does not affect timing and sensing behavior of the pulse generator. Synchronous operation is of particular importance during follow-up, if sensing and inhibition functions are desired during magnet application.

Trend monitor and event counter operation is interrupted during magnet application with either 'Asynchronous' or 'Synchronous' magnet effect.

9.3 Real-time IEGM Transmission and Marker Signals

The IEGM sampling rate is 256 Hz if both the atrial and ventricular electrograms are recorded and 512 Hz if only one electrogram is used. The IEGMs may be transmitted to the programmer via the programming head positioned over the implanted pacemaker. They are then displayed together with surface ECG and markers on the programmer screen and printed on the ECG recorder. Likewise, markers identifying atrial/ventricular paced and sensed events are received via the programming head, and may be displayed on the programmer screen and printed on the ECG recorder.

Please refer to the appropriate software technical manual for a description of marker signal operation

9.4 Temporary Programming

A temporary program is a pacing program which remains activated while the programming head is positioned over the pulse generator; upon removal of the programming head (at least 10 cm away from the pacemaker) the temporary program will be automatically deactivated and the permanent program will again be in effect

Generally, every pacing program displayed on the programmer screen may be transmitted as a temporary program by pressing the key designated on the programmer keyboard. With few exceptions this also applies to pacing programs containing a parameter conflict which cannot be programmed as permanent programs. Temporary programming facilitates follow-up and enhances patient safety. Test programs affecting patient safety, like pacing threshold measurements in a pacemaker-dependent patient, should be activated as a temporary program only.

When interrogating the pacemaker, the permanent program will always be displayed and documented, even though a temporary program was activated during the interrogation.

During magnet application (i.e., during temporary program activation) the rate adaptation, trend monitor, and the event counter are always inactive.

9.5 Threshold Test

The pacemaker is equipped with a high-precision threshold test ranging from 4.8 V to 0.1 V. The test is activated as a temporary program with specific operation as defined by the applicable software version. Removal of the programmer head immediately stops the test and reactivates the permanent program. When using this function, the pacing rate should be set higher than the spontaneous rate to ensure pacing. Please refer to the

appropriate software technical manual for a description of threshold test operation.

9.6 Battery and Lead Telemetry

Noninvasive measurements of battery and lead pulse parameters are available with these pacemaker models. Measurement tests are performed asynchronously at the magnet rate. In the Dromos DR/DR-A, lead data are available in both the atrial and ventricular channels. The parameters measured and displayed by the programmer are:

Parameter	Measurement Units	Tolerance*
Battery voltage	V	± 3%
Battery impedance	kOhm	± 15%
Battery current	µA	± 2 µA ± 5%
Lead pulse voltage	V	± 0.2 V ± 5%
Lead pulse current	mA	± 1 mA ± 20%
Lead pulse charge	µC	± 20%
Lead pulse energy	µJ	± 20%
Lead lead impedance	Ohm	± 20%

*Tolerances are applicable for Standard Program (4.8 V pulse amplitude, 0.5 ms pulse width, 60 ppm basic rate) at the time of manufacturing.

See Section 13 "Elective Replacement Indication" to determine battery depletion by means of the magnet rate

9.7 Patient Data Memory

The pacemaker provides storage of individual patient data in the pacemaker's memory. The stored data is automatically displayed upon each interrogation. The range and type of data to be stored is determined by the software module being used. The patient data memory contains the following data categories:

- Patient Code
- Symptom
- Etiology
- ECG Indication

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- Date of Last Follow-up
- Lead Polarity (Atrial/Ventricular)
- Implantation Date

The lead polarity setting has an added safety feature which prevents the programming of bipolar configuration unless bipolar leads have been documented within the patient data memory. For further information regarding lead and pacemaker polarity programming conflicts, please refer to the appropriate software technical manual.

WARNING

The Dromos DR / SR pacemaker can be operated with either unipolar or bipolar IS-1 leads. If the pacing or sensing function is to be programmed **bipolar** for either chamber, it must be verified that **bipolar leads** have been implanted in the respective chamber. If either of the leads is unipolar, unipolar sensing and pacing functions must be programmed in that chamber. Failure to do this results in an entrance and/or exit block for the chamber(s) with unipolar lead(s).

In addition, if the lead polarity setting within the Patient Data Memory has been set to **bipolar**, the polarity of the corresponding implanted lead(s) must be confirmed to be **bipolar**.

Symptom, etiology and ECG indication are specified using the European PASSPORT code system. The PASSPORT code is an identification system of two character codes which represent specific conditions. A listing of the codes available with definitions is displayed on the screen of the programmer when patient data is selected. The patient data screen is entered when symptom, etiology, or ECG indication are being programmed, and can be entered following interrogation to check code definition.

For further information on the patient data memory features, please refer to the software manual for the software version used.

9.8 Event Counter

The event counter can count the following events:

- Dromos DR: A-sense, A-pace, V-sense, V-pace, and PVC (ventricular sensed event outside of the AV delay)
- Dromos SR: Sense, pace

Upon interrogation, the total number of events as well as the relative number with respect to all events counted (expressed as a percentage) in the corresponding chamber are displayed. Up to 16,777,215 events of each type can be counted. If one counter reaches its maximum, all other counters are stopped.

Upon magnet application, the counting of events is interrupted temporarily, regardless of the selected magnet effect.

NOTE:

Reprogramming of the mode may affect the number of each type of event counted by the pacemaker. Premature ventricular contractions (PVCs) are counted both as PVCs and as ventricular sense events.

9.9 Trend Monitor and Sensor Simulation

The trend monitor provides a rate profile in which sensed and paced events occur over time and enables recording of the heart rate during exercise tests or daily activities (Figure 15).

The desired duration of a trend is programmable in the ranges provided below. A complete recording consists of 128 data points, each of which represent the average rate over the time interval defined by the trend duration

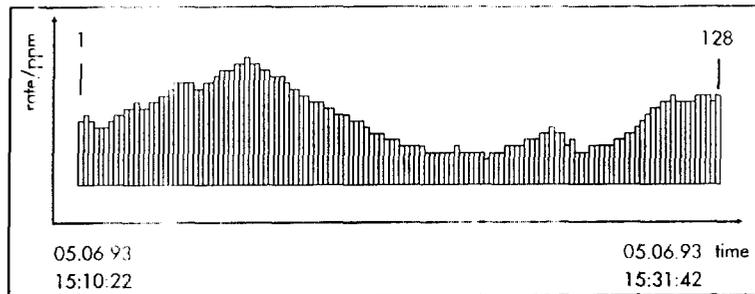


Figure 15. Trend monitor displaying the rate as a function of time.

Trend recording can be performed in the rolling or fixed modes. In rolling mode, the collected data is continuously updated such that the rate profile originating from the period of time preceding interrogation is displayed upon interrogation. In fixed mode, the trend monitor stops after the first 128 data points are stored so that the rate profile from the period of time immediately following initiation of the trend monitor is displayed upon interrogation. In both cases, start and stop time are automatically recorded and displayed.

For special applications, the memory available for trend recording can be split into two independently programmable trend monitors, which allows recording of two different trends in parallel. Instead of 128 data points, 64 data points are then available for each of the two trend monitors. Event types to be counted and recording time can be independently selected.

The activation of "sensor simulation" (programmed "ON") from the main program screen, when in non-rate adaptive modes, allows the trend monitor to indicate how the sensor would have responded if a rate adaptive mode was selected. This function can be useful in finding the optimal sensor settings and in comparing the sensor rate with the intrinsic rate.

Upon magnet application, the counting of events is interrupted temporarily, independent of the selected magnet effect. Regardless of magnet application, the reference time is continually counted. Therefore, the recorded rate is less than the actual rate for the corresponding time period.

For further information on the trend monitor, please refer to the appropriate software version manual.

Counted event:

Dromos DR/DR-A: A-sense, A-pace, V-sense, V-pace,
A-sense + A-pace, V-sense + V-pace,
simulation

Dromos SR/SR-B: sense, pace, sense+pace, simulation

Recording time: 20 min, 1 hr, 2 hr, 4 hr, 10 hr, 20 hr, 64 hr,
128 hr (the specified recording times are
divided by two when splitting the Trend Monitor)

Mode: rolling, fixed

Event counter: 1 counter, 2 counters

NOTE:

The recording times specified are approximate, i.e., 1280 seconds (actual) has been rounded off to 20 minutes. The actual recording time is always greater than the stated recording time.

9.10 Position Indicator

The position indicator facilitates positioning of the programmer head. The programmer optically indicates whether the programmer head is within communication range of the pulse generator.

9.11 Automatic PMT Prevention/ Termination

(Dromos DR-DR-A only)

A "circus movement" pacemaker-mediated tachycardia (PMT) is perpetuated retrogradely by VA-conduction of the paced ventricular depolarization and antegradely by P-wave triggered ventricular pacing, as provided, for example, in the DDD mode. Since PMTs are usually initiated by a ventricular depolarization asynchronous with atrial depolarization (a premature ventricular

contraction, PVC), a ventricular sensed event outside of the AV delay resets the lower rate interval and the atrial refractory period (ARP). This prevents a retrograde P-wave with a VA conduction time shorter than the ARP from triggering a ventricular pacing pulse (Figure 16).

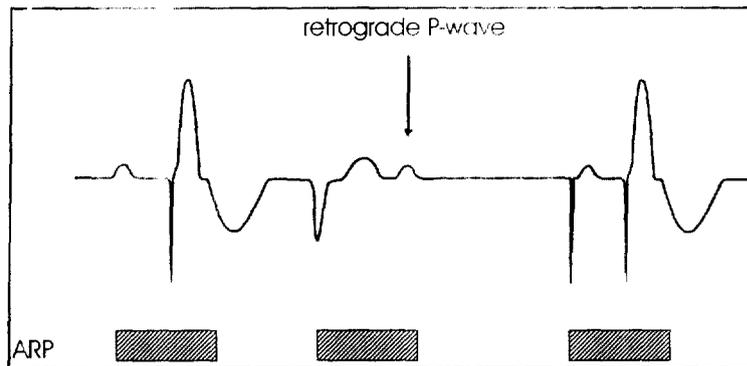


Figure 16. Prevention of PMT by PVC starting ARP (DDD mode)

The dynamic AV delay also serves for prevention/termination of PMT by rate-dependent shortening of the AV delay resulting in a corresponding prolongation of the postventricular atrial refractory period (PVARP). An example is shown in Figure 17.

In the presence of an (intermittent) atrial exit block, the paced ventricular depolarization is not preceded by an atrial depolarization permitting retrograde conduction to occur. The retrogradely conducted P-wave falls outside of the ARP because of the relatively short PVARP during AV sequential pacing. Because of the short coupling interval to the preceding atrial event, the AV delay is shortened and the corresponding PVARP prolonged so that the second retrogradely conducted P-wave falls within the PVARP preventing further "circus movement".

VA³

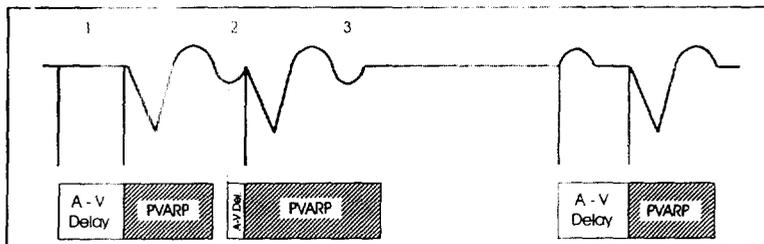


Figure 17. Dynamic AV delay for PMT prevention: 1 = Intermittent atrial exit block permitting retrograde conduction, 2 = Retrograde P-wave falls outside of the PVARP (for AV sequential pacing), 3 = Retrogradely conducted atrial depolarization falling inside of the prolonged PVARP.

For PMT prevention, the PVARP must be longer than the retrograde conduction time after the paced ventricular depolarization. The duration of the PVARP depends on the duration of the ARP and the (rate-dependent) duration of AV delay ($PVARP = ARP \text{ minus AV delay}$). The programming software provides three slope settings ("low", "medium", and "high") of the dynamic AV delay. If programmed to the "medium" slope of the dynamic AV delay, for example, in an otherwise standard DDD program having an ARP of 400 ms, the AV delay shortens to 75 ms at atrial rates exceeding 130 ppm. This results in a prolongation of the PVARP to 325 ms.

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10. Product Storage and Handling

10.1 Sterilization and Storage

The pacemaker is shipped in a cardboard box, equipped with a quality control seal and product information label. The label contains the model specifications, technical data, serial number, expiration date, and sterilization and storage information of the pacemaker.

The pacemaker and its accessories have been sealed in a container and gas sterilized with ethylene oxide. To assure sterility, the container should be checked for integrity prior to opening. If resterilization becomes necessary, contact your local BIOTRONIK representative.

CAUTION

If resterilization is necessary, use only ethylene oxide at temperatures not exceeding 55° C (131° F), and aerate the packaged device until the concentration of ethylene oxide residue is below the level prescribed by applicable federal and/or state laws. In the absence of applicable requirements, refer to AAMI GVR-1987, Good Hospital Practice: Ethylene Oxide Gas - Ventilation Recommendations and Safe Use.

Do not use steam sterilization (flash) or autoclave a pulse generator.

CAUTION

Recommended storage temperature range is 5°C to 55°C (41° - 131°F). Exposure to temperatures outside this range may result in pacemaker malfunction.

CAUTION

Exposure to **low temperatures** (below 0°C) may cause a false elective replacement indication to be present. If this occurs, warm the device to room temperature and reset the ERI with magnet application. Upon removal of the magnet, the elective replacement indication should not be present. If the elective replacement indication remains, return the pulse generator to BIOTRONIK.

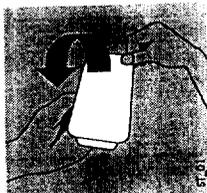
Do not drop. If an unpackaged pulse generator is dropped onto a hard surface, return it to BIOTRONIK.

Do not resterilize a pulse generator or packaged that becomes contaminated by contact with body fluids.

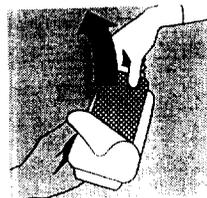
Accessories packaged with the pulse generator are intended for one-time use. Do not resterilize them.

10.2 Opening the Sterile Container

The pacemaker is packaged in two plastic containers, one within the other. Each is individually sealed and then sterilized with ethylene oxide. Due to the double packing, the outside of the inner container is sterile and can be removed using standard aseptic technique and placed on the sterile field.



Peel off the sealing paper of the outer container as indicated by the arrow.



Take out the inner sterile container by the gripping tab and open it by peeling the sealing paper as indicated by the arrow.

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10.3 Insulative Coating

The pulse generators have an external insulative coating of silicone to minimize the potential for muscle stimulation at the implant site if the unit is programmed to unipolar pacing.

Care should be taken not to damage the insulative coating during the implant procedure. The pulse generator should be implanted with the window over the logo facing away from adjacent skeletal muscle mass to minimize the potential for pocket stimulation and myopotential sensing in the unipolar pacing and sensing polarities, respectively.

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11. Lead Connection

11.1 Dromos DR and Dromos SR

NOTE:

3.2 mm connecting systems which do not expressly claim to agree with the IS-1 dimensions generally have to be regarded as incompatible with IS-1 connectors and can only be used with BIOTRONIK products together with an appropriate adapter. For questions regarding lead-generator compatibility, consult your BIOTRONIK representative.

Dromos DR dual-chamber pacemaker has been designed and is recommended for use with atrial or ventricular bipolar leads having an IS-1 connector. The Dromos SR single-chamber pacemaker has been designed and is recommended for use with atrial or ventricular bipolar leads having an IS-1 connector. The IS-1 receptacle also permits the connection of unipolar leads with an IS-1 connector pin.

WARNING

The Dromos DR and Dromos SR pacemakers can be operated with either unipolar or bipolar IS-1 leads. If the pacing or sensing function is to be programmed bipolar for either chamber, it must be verified that **bipolar leads** have been implanted in the respective chamber. If either of the leads is unipolar, unipolar sensing and pacing functions must be programmed in that chamber. Failure to do this results in an entrance and/or exit block for the chamber(s) with unipolar lead(s).

In addition, if the lead polarity setting within the Patient Data Memory has been set to **bipolar**, the polarity of the corresponding implanted lead(s) must be confirmed to be **bipolar**.

NOTE:

In case of pacemaker replacement, make sure that the existing lead connector is not damaged.

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BIOTRONIK recommends the use of bipolar pacing leads so that all of the programmable parameters of these generators are available for use.

The Dromos DR/SR pacemaker has a self-sealing header. Refer to the following steps when connecting a lead(s) to the pacemaker.

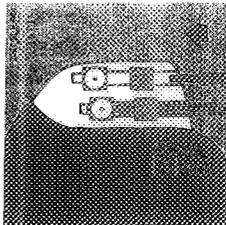
First, confirm that the setscrew(s) is not protruding into the connector receptacle. To retract a setscrew, insert the enclosed torque wrench through the perforation in the self-sealing plug at an angle perpendicular to the lead connector until it is firmly placed in the setscrew.

CAUTION

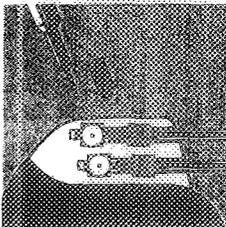
Retract the setscrew(s) slightly to ensure unimpeded insertion of the lead connector(s) into the port(s). Failure to back-off the setscrew(s) may result in damage to the lead(s), and/or difficulty connecting the lead(s).

Rotate the wrench counterclockwise until the receptacle is clear of obstruction. Then:

Dromos DR

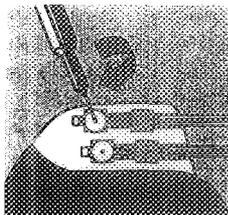


Insert the lead connector into the connector receptacle of the pacemaker without bending the lead until the connector pin becomes visible behind the setscrew. Hold the connector in this position.



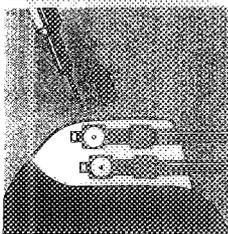
Insert the enclosed torque wrench through the perforation in the self-sealing plug at an angle perpendicular to the lead connector until it is firmly placed in the setscrew.

CAUTION: Failure to properly insert the torque wrench into the perforation at an angle perpendicular to the connector receptacle may result in damage to the plug and its self-sealing properties.

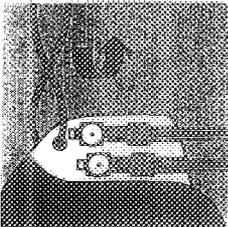


Securely tighten the setscrew of the connector clockwise with the torque wrench until torque transmission is limited by the wrench.

CAUTION: Do not overtighten the setscrew. Use only a torque wrench supplied by manufacturer which automatically prevents over-tightening.

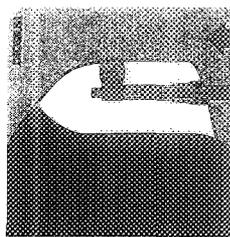


After retracting the torque wrench, the perforation will self-seal. The proximal electrode of bipolar leads is automatically connected. Connect the second lead as described above.

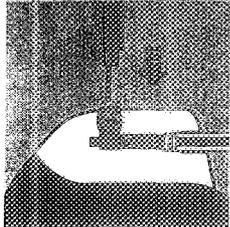


Pass nonabsorbable ligature through the hole in the connector receptacle to fix the pacemaker in the pocket.

Dromos SR



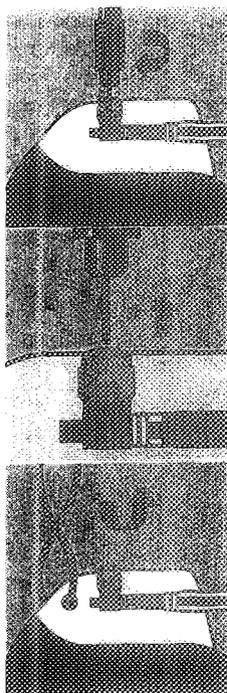
Insert the lead connector into the connector receptacle of the pacemaker without bending the lead until the connector pin becomes visible behind the setscrew. Hold the connector in this position.



Insert the enclosed torque wrench through the perforation in the self-sealing plug at an angle perpendicular to the lead connector until it is firmly placed in the setscrew.

CAUTION: Failure to properly insert the torque wrench into the perforation at an angle perpendicular to the connector receptacle may result in damage to the plug and its self-sealing properties.

Handwritten initials or mark.



Securely tighten the setscrew of the connector clockwise with the torque wrench until torque transmission is limited by the wrench.

CAUTION: Do not overtighten the setscrew. Use only a torque wrench supplied by manufacturer which automatically prevents over tightening.

After retracting the torque wrench, the perforation will self-seal. The proximal electrode of bipolar leads is automatically connected.

Pass nonabsorbable ligature through the hole in the connector receptacle to fix the pacemaker in the pocket.

11.2 Dromos DR-A and Dromos SR-B

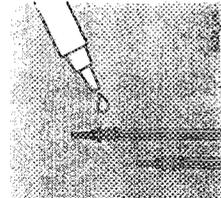
The Dromos DR-A is a dual-chamber pacemaker which has been designed for and is recommended for use with atrial or ventricular **unipolar** leads having a 5 mm Pin-Lock[®] PE connector. The Dromos SR-B is a single-chamber pacemaker which has been designed for and is recommended for use with an atrial or ventricular **unipolar** lead having a 6 mm Pin-Lock[®] PEC connector. Using the PEH upsizing sleeve supplied with the pacemaker, an unipolar 5 mm PIN-Lock[®] PE connector lead can be connected.

CAUTION

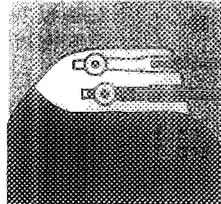
Retract the setscrew(s) slightly to ensure unimpeded insertion of the lead connector(s) into the port(s). **Failure** to back-off the setscrew(s) may result in damage to the lead(s), and/or difficulty connecting the lead(s).

Refer to the following steps when connecting a lead(s) to the pacemaker.

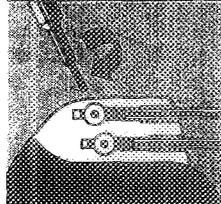
Dromos DR-A



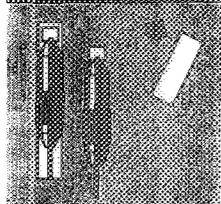
Lubricate the proximal and distal sealing rings of the connector with silicone oil.



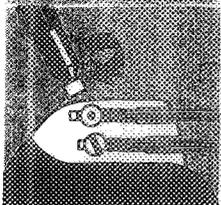
Insert connector(s) into the connector receptacle(s) of the pacemaker without bending the lead(s) until the connector pin(s) becomes visible behind the setscrew(s). Insert the atrial lead into the upper connector and the ventricular lead into the lower connector. Hold the connector in this position.



Securely tighten the setscrew(s) of the connector(s) clockwise with the torque wrench provided by the manufacturer until torque transmission is limited by the wrench.

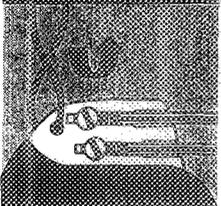


Pull off the sleeve from the handle of the torque wrench and attach it to the top of the hex wrench.



Seal the setscrew(s) by securely tightening the sealing cap(s) clockwise for compression of the O-shaped silicone ring(s).

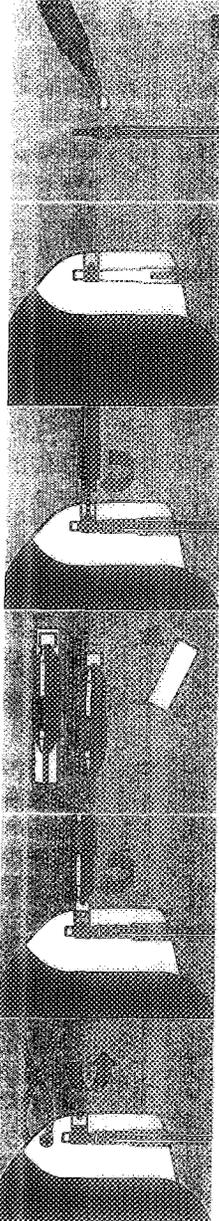
CAUTION: The setscrew(s) must be sealed with the sealing cap(s) provided. If the setscrew(s) is not sealed, pacemaker malfunction may occur.



Pass nonabsorbable suture through the hole in the connector receptacle to fix the pacemaker in the pocket.

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Dromos SR-B



Lubricate the proximal and distal sealing rings of the connector with silicone oil

Insert the connector into the connector receptacle of the pacemaker without bending the lead until the connector pin becomes visible behind the setscrew. Insert the lead into the connector. Hold the connector in this position.

NOTE: When using a 5 mm lead connector with a Dromos SR-B, attach a PEH upsizing sleeve adapter to the 5 mm lead before inserting it into the pacemaker receptacle.

Securely tighten the setscrew of the connector clockwise with the torque wrench provided by the manufacturer until torque transmission is limited by the wrench.

Pull off the sleeve from the handle of the torque wrench and attach it to the top of the hex wrench.

Seal the setscrew by securely tightening the sealing cap clockwise for compression of the O-shaped silicone ring

CAUTION: The setscrew must be sealed with the sealing cap provided. If the setscrew is not sealed, pacemaker malfunction may occur.

Pass nonabsorbable ligature through the hole in the connector receptacle to fix the pacemaker in the pocket.

12. Follow-up Procedures

12.1 General Considerations

The pacemaker follow-up serves to verify appropriate function of the pacing system, and to optimize the parameter settings.

The likelihood of an electronic defect or premature battery depletion is extremely low. Pacing system malfunction attributed to other causes such as chronic threshold rise is considerably more probable. In most instances, such problems can be corrected by re-programming the pacemaker. The follow-up intervals are, therefore, primarily determined by medical judgement, taking possible pacemaker dependency into consideration.

The following notes are meant to stress certain product features which are of importance for follow-up. For detailed information on follow-up procedures and medical aspects, please refer to the pertinent medical literature.

12.2 Testing the Pacing Function

The pacemaker models are equipped with a threshold test over the range of 0.1 and 4.8 V with a precision of 0.1 V. The threshold test is a temporary program whose specific operation is defined by the applicable software version. The threshold is determined by observing the ECG. Likewise, all determinations of threshold or threshold margin, by any means, should only be performed by use of temporary programming to permit immediate reactivation of the permanent program in case of loss of capture. Please refer to the appropriate software technical manual for a description of the threshold test operation.

The threshold test should be performed with the pulse width selected for the permanent program. To ensure pacing, the pacing rate of the threshold test program should exceed the patient's intrinsic rate.

To determine the threshold, the ECG must be observed continuously. Based on the measured threshold, the pulse amplitude for the permanent program should be adjusted. Please consult the pertinent medical literature for specific recommendations regarding necessary safety margins.

12.3 Testing the Sensing Function

To permit evaluation of the sensing function, the pacing rate must be lower than the patient's intrinsic rate. In demand pacing, the proper sensing function can be recognized if the interval between intrinsic events and the following pacing pulse equals the basic interval (if no Hysteresis is programmed).

For evaluation of the sensing function, the pacemaker features an intracardiac electrogram (IEGM) to indicate sensed and paced events. Additionally, triggered pacing modes can be selected which, synchronously to the detection of an intrinsic event, emit a pacing pulse and mark the sensed event and its timing on the ECG.

For evaluation of the sensing function, event markers indicating sensed and paced events are available.

Especially with unipolar sensing functions, the selected sensitivity level should be checked for possible interference from skeletal myopotentials. If oversensing is observed, the programming of a lower sensitivity (higher value), or bipolar sensing function, if the implanted lead is bipolar, should be evaluated.

12.4 Analog Telemetry

The pacemaker provides the capability to transmit non-invasive analog data. In addition to the intracardiac electrogram with marker signals, the measured battery voltage, lead impedance, and current consumption in the selected pacing programs can be displayed and documented via the programmer. By measuring the current consumption, the most energy conserving

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combination of pulse amplitude and pulse width can be determined. The analog telemetry provides additional information which can be utilized for the interest of patient safety and, therefore, should be used at every follow-up.

12.5 Testing for Retrograde Conduction

(Dromos DR/DR-A only)

Retrograde conduction from the ventricle to the atrium can be assumed when a 1:1 relationship between the ventricular stimulation and atrial depolarization has been obtained with a constant coupling interval during ventricular stimulation. A ventricular pacing rate well above the intrinsic rate of the atrium has to be selected. The VDI or DDI/T modes of the Dromos DR/Dromos DR-A can be used to measure the retrograde conduction time.

The retrograde conduction time between ventricular pacing and atrial sensing can be measured directly on the screen or printer of the programmer, using either VDI or DDI/T modes.

To prevent retrograde P-waves from triggering ventricular pulses in atrial tracking modes, thereby mediating a "re-entry" tachycardia (pacemaker mediated tachycardia, PMT), the programmed post-ventricular atrial refractory period must be longer than the retrograde conduction time.

12.6 Optimizing Rate Adaptation

It is recommended to check the parameters controlling rate adaptation during each follow-up for their individual therapeutic suitability. Any intermediate change in the patient's general well-being and cardiac performance since the last follow-up should be taken into consideration. It must be assured that in all cases, the settings for sensor gain, maximum sensor rate, rate increase and rate decrease are well tolerated by the patient.

A

Use of the trend monitor for recording the pacing and/or intrinsic rate during follow-up and during daily activities facilitates evaluation of the parameter settings for rate adaptation. The rolling mode of the trend monitor is particularly useful during follow-up since the time period immediately preceding the follow-up may be evaluated.

When in doubt about the suitability of particular sensor settings for a certain patient, the sensor simulation can be utilized to observe the sensor response without the sensor actually controlling the pacing rate. The simulation of the sensor activity can be recorded (in non-rate adaptive modes) with the trend monitor

12.6.1 Adjusting the Sensor Gain

The sensor gain controls the change in stimulation rate for a certain change in work load detected by the sensor. An exercise test is recommended in order to achieve a rate response *proportional to work load* by optimizing the sensor gain. If the pacing rate tends to be too high for the specific amount of work load or if the selected maximum sensor rate is achieved at too low of an exercise level, the sensor gain should be reduced by selecting a lower gain setting. If, on the other hand, rate adaptation is insufficient for a specific amount of workload, selection of a higher gain setting may be indicated. The trend monitor can be used to record the pacing rate during exercise.

12.6.2 Adjusting the Sensor Threshold

The sensor threshold controls the (motion) signal level that has to be exceeded to cause a rate increase. This parameter is meant to assure a stable pacing rate at rest and to prevent rate increases at signal levels not consistent with physical exertion. The sensor gain should be optimized prior to adjusting the sensor threshold. Otherwise, changing of the gain setting will *cause changes in the effective threshold*

If rate increase is caused by low level activities, when no rate adaption is desired, the sensor threshold setting should be increased by selecting the next higher setting (e.g., low to mean). If, on the other hand, the pacemaker tends to respond only at

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higher levels of work, a reduction of the sensor threshold may be indicated (e.g., high reduced to mean). The trend monitor can be used to record the pacing rate at rest.

12.6.3 Suggested Procedure for Sensor Parameter Optimization

1. Reprogram to rate adaptive mode at nominal sensor settings.
2. Program trend monitors:
 - Rolling mode
 - Two trend monitors - atrial sense and atrial pace
 - Counter run of 10 minutes
3. Start trend monitoring registers.
4. Ask patient to perform a normal pace walk for two minutes. Ask patient to rest for one minute.
5. Interrogate the trend monitor and obtain a printout.
6. Analyze the printout for pacing rates. The pacing rate should increase above the programmed basic rate 25 ± 5 ppm, but should not go to the maximum sensor rate. If the sensor rate did not increase, adjust the sensor gain, reset and clear all trend counter registers. Repeat steps until a rise in pacing rate is seen to 25 ± 5 ppm, that does not go to the maximum sensor rate. If the sensor rate increased to the maximum sensor rate with exercise, decrease the sensor gain. Repeat steps until the pacing rate increase is seen to 25 ± 5 ppm.
7. Clear and start trend monitor registers
8. Ask patient to exercise at a high level of activity (brisk walk or stair climbing) for two minutes. Ask patient to rest for one minute, interrogate the trend monitor and obtain a printout.
9. Confirm via the printout that pacing is within 15 ppm of the maximum sensor rate is achieved during this exercise. If the maximum sensor rate is not within 15 ppm, increase sensor gain and repeat steps. Reset the trend monitor before each repeated test.

13. Elective Replacement Indication

The service time of the pacemaker varies based on several factors, including battery properties, storage time, lead system impedance, programmed parameters, relative amount of pacing and sensing required, and circuit operating characteristics. Service time is the time from beginning of service (BOS) to the end of service (EOS). To assist the physician in determining the optimum time for pacemaker replacement, two replacement indicators are provided that are activated when the battery cell voltage drops to predetermined levels. The following table defines the different service cycles (at standard settings, 37° C, 500 ohms). The beginning of the replacement cycle is displayed on the programmer after interrogation and appears on the printout.

Service Cycle Definitions

Abbreviation	Service Cycle	Definition
BOS	Beginning of Service	Normal service cycle; battery in good condition
ARI	Anticipated Replacement Indication	Identifies the time when elective replacement indication is not yet reached, but is approaching.
ERI	Elective Replacement Indication	Identifies the time of elective replacement indication. The rate occurring at ERI depends upon the programmed mode and magnet application.
EOS	End of Service	Identifies the end of the elective replacement indication period.

The pacemaker indicates the need for replacement by a defined decrease of its rate after magnet application and by a note on the programmer (printout). The replacement indication is reached if immediately after magnet application 10 cycles are paced at a rate

of 80 ppm (750 ms). In the time between ARI and ERI, the first 2 cycles immediately after magnet application are paced at a rate of 90 (667 ms). The next 8 cycles, at a minimum have a rate of 80 ppm (750 ms)

Elective Replacement Indication (ERI)

Magnet	Modes	Response
Yes	DDDR, VDDR, VVIR (SSIR), AAIR (SSIR), DOOR, VOOR (SOOR), AOO (SOOR)	10 Cycles at 80 ppm, then pacing at programmed lower rate.
Yes	DDD, VDD, DOO, VVI (SSI), AAI (SSI), VOO (SOO), AOO (SOO), DDT, VDT, VVT (SST), AAT (SST), VDI	10 cycles at 80 ppm, then pacing at 11% reduction of lower rate
Yes	DDIR, DDI, DVIR, DVI, DDET, DVT	10 cycles at 80 ppm, then continued pacing at 80 ppm with magnet.
No	Rate Adaptive Modes	Programmed lower rate unchanged
No	Non Rate Adaptive Modes	Programmed lower rate reduced by up to 11%.

If the pacemaker is programmed to a dual-chamber pacing mode (Dromos DR/DR-A), only ventricular pacing will occur (atrial sensing function and rate adaptation remain intact) when reaching the recommended replacement indication:

Programmed Mode	Mode At Replacement Indication
DDD(R)	VDD(R)
DVI(R)	VVI(R)
DDI(R)	VVI(R)
DDT	VDT
DVT	VVT
DDET	VVT
DOO(R)	VOO(R)

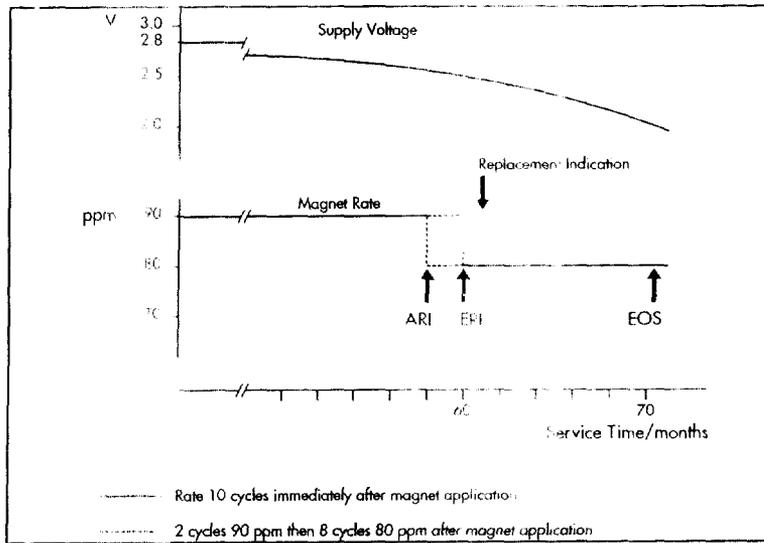


Figure 18. Battery voltage and magnet rate related to the service time.

Nominal Pacemaker Longevity (BOS-ERI):

	Dromos DR/DR-A	Dromos SR/SR-B
Factory Program ¹	60 months	86 months
Standard Program ²	56 months	80 months
High Output Program ³	30 months	50 months

The following table shows the mean⁴ and the minimum⁵ expected time intervals (in months) from ARI to ERI and from ERI to EOS at standard program and high output program settings for the Dromos DR. All service intervals, including the above cited nominal pacemaker longevity, are based on statistical considerations taking into account the battery discharge behavior and the hybrid circuit's properties including current consumption and

¹ Factory: (DR) DDD, 60 ppm, 4.8 V, 0.5 ms; (SR) SSI, 60 ppm, 4.8 V, 0.5 ms
² Standard: (DR) DDDR, 60 ppm, 4.8 V, 0.5 ms; (SR) SSIR, 60 ppm, 4.8 V, 0.5 ms
³ High output: (DR) DDDR, 90 ppm, 4.8 V, 1.0 ms; (SR) SSIR, 90 ppm, 4.8 V, 1.0 ms
⁴ 50% of all pacemakers reach or exceed the given value
⁵ 99.9% of all pacemakers reach or exceed the given value (-3σ)

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replacement indicator. The statistical calculations are based on a 500 ohm load, 100% pacing, and data supplied by the battery manufacturer. With a 300 ohm load, the service times stated below are decreased by a maximum of 30%.

Service Cycles for Dromos DR/DR-A

Pacing Program	ARI to ERI (months)	ERI to EOS (months)
Standard Program ¹ , Mean	2	11
Standard Program, 99.9%	2	8
High Output ² Mean	0	12
High Output, 99.9%	0	9

Service Cycles for Dromos SR/SR-B

Pacing Program	ARI to ERI (months)	ERI to EOS (months)
Standard Program ³ , Mean	2	8
Standard Program, 99.9%	1	6
High Output ⁴ Mean	0	9
High Output, 99.9%	0	7

CAUTION

Programming of pulse amplitudes, higher than 4.8 V, in combination with long pulse widths and/or high lower rates, even with batteries in the BOS state, can lead to premature activation of the replacement indicator. If a pulse amplitude of 7.2 V or higher is programmed and high pacing rates are reached, output amplitudes may differ from programmed values.

¹ Standard program: DDDR, 60 ppm, 4.8 V, 0.5 ms

² High output: DDDR, 90 ppm, 4.8 V, 1.0 ms

³ Standard program: SSIR, 60 ppm, 4.8 V, 0.5 ms

⁴ High output: SSIR, 90 ppm, 4.8 V, 1.0 ms

NOTE:

When the battery voltage has only transiently decreased below the value set for elective replacement indication, closing and opening the reed switch (magnet application and removal) will cancel the replacement indication, i.e. the (lower) rate and the pacing mode will again be as programmed. The replacement indication, if present, will be indicated on the display of the programmer when interrogating the pacemaker.

14. Explantation

Explanted pacemakers or explanted accessories may not be reused. Explanted pacemakers can be sent either to the local BIOTRONIK representative or the BIOTRONIK home office for expert disposal. If possible, the explanted pacemaker should be cleaned with a sodium-hyperchlorine solution of at least 1% chlorine and thereafter, washed with water prior to shipping.

The pulse generator should be explanted before the cremation of a deceased patient.

15. Precautionary Notes

The pulse generator, with the lead(s) and if applicable, implanted lead extensions and adapters, become the artificial pacing system. All of these components, along with their interface to the cardiac tissue and the physiological condition of the patient, determine the function of the pacing system.

The following notes emphasize certain aspects which may be of importance for the evaluation and avoidance of risks to the patient. However, please refer to related medical literature for specific details of each subject mentioned.

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15.1 Myopotential Sensing

The filter characteristics of BIOTRONIK pulse generators have been optimized to sense electrical potentials generated by cardiac activity and to reduce the possibility of sensing skeletal myopotentials. However, the risk of pacemaker operation being affected by myopotentials cannot be eliminated, particularly in unipolar systems. Myopotentials can mimic cardiac activity, resulting in pacemaker pulse inhibition, triggering and/or emission of asynchronous pacing pulses, depending on the pacing mode and the interference pattern.

Certain follow-up procedures, such as monitoring pacemaker performance while the patient is doing exercises involving the use of pectoral muscles, as well as Holter monitoring, have been recommended to check for interference caused by myopotentials. If sensing of myopotentials is encountered, corrective actions, depending on the options available, may include, but are not limited to, selection of a different pacing mode or sensitivity.

15.2 Common Reasons for Pacemaker Explant

A pulse generator may be explanted emergently or at a physician's discretion at any time subsequent to an implant procedure. Reasons for explant include, but are not limited to: patient death; no output/intermittent output; loss of capture/ sensing; inability to program/interrogate the pulse generator; infection, EOS (normal or premature); system upgrade; physician preference for another pacemaker model; and/or other reason(s) which may or may not be known to the pacemaker manufacturer. Complications related to other portions of the pacing system (i.e., lead, patient) may also result in pacemaker explant. The table on the following page summarizes some of the more common reasons for pacemaker explant.

Source	Cause	Possible Effect
Battery	Premature depletion due to high programmed output or other cause(s) resulting in excessive battery current drain.	Output voltage decrease; rate decrease; loss of capture; increased pulse width; inability to program/interrogate; sensing difficulty
Circuitry	Electrical parameter changes due to shorts, opens, or component parametric drift Electromagnetic Interference (EMI) from large power tools, industrial equipment, electrocautery, defibrillation, radiation therapy, RF ablation therapy, etc.	No output; rate increase, rate decrease; reversion to asynchronous mode; loss of capture and/or sensing Permanent or temporary loss of output; output inhibition; reversion to asynchronous mode with rate change or instability; pacing synchronized to interference; reversion to "Elective Replacement" or electrical reset parameters; inability to program/interrogate; other damage to circuit components resulting in permanent or temporary parameter changes
Connector, setscrews, etc.	Poor connection, intrusion of body fluid	Excessive current drain; early battery depletion; intermittent or continuous loss of capture and/or sensing
Leads	Displacement, fracture, loss of insulation integrity Cardiac perforation Myocardial irritability at time of insertion, e.g., from an acute myocardial infarction	Intermittent or continuous loss of capture and/or sensing; excessive current drain: early battery depletion The above plus cardiac tamponade; muscle or nerve stimulation Fibrillation
Patient	Threshold Elevation Normal medical complication Body rejection phenomena	Loss of capture and/or sensing Infection Fluid accumulation; migration; erosion
Misc.	Unipolar pacing systems Physician preference Introducer caused	Inhibition of pulse generator due to sensing of skeletal muscle activity Upgrade to bipolar, dual-chamber, rate adaptive pulse generator, etc. Air embolism or pneumothorax

15.3 Electromagnetic Interference (EMI)

The operation of any implanted pulse generator can be affected by certain environmental sources generating signals that mimic cardiac activity. This can result in pacemaker pulse inhibition and/or triggering or in asynchronous pacing depending on the pacing mode and the interference pattern. In some cases (i.e., diagnostic or therapeutic medical procedures), the interference sources can couple sufficient energy into a pacing system to damage the pulse generator and/or cardiac tissue adjacent to the electrodes.

BIOTRONIK pulse generators have been designed to significantly reduce susceptibility to electromagnetic interference (EMI). However, due to the variety and complexity of sources creating interference, there is no absolute protection against EMI. Generally, it is assumed that EMI produces only minor effects, if any, in pacemaker patients. If the patient presumably will be exposed to one of the following environmental conditions, then he should be given the appropriate warnings.

15.3.1 Home Appliances

Home appliances normally do not affect pacemaker operation if the appliances are in proper condition and correctly grounded and encased. There are reports of pacemaker disturbances caused by electrical tools and by electric razors which have touched the skin directly over the pulse generator.

15.3.2 Job and Special Environments

The following equipment (and similar devices) may affect normal pacemaker operation: electric arc welders, electric melting furnaces, radio/television and radar transmitters, power-generating facilities, high-voltage transmission lines, electrical ignition systems (also of gasoline-powered devices) if protective hoods, shrouds, etc., are removed, electrical tools, anti-theft devices of shopping centers and electrical appliances, if not in proper condition or not correctly grounded and encased.

15.4 Pacing When Exposed to Interference

A sensed event occurring during the interference interval will continuously reset that interval for the corresponding chamber without resetting the basic interval. Depending upon whether the interference (electromagnetic interference, muscle potentials, etc.) is detected by the atrial and/or ventricular channel, atrial and/or ventricular asynchronous pacing at the programmed timing intervals will result for the duration of the interference.

Depending on the programmed pacing mode and the channel in which electromagnetic interference (EMI) occurs, the following pacing modes will result for the duration of the exposure:

MODE	EMI* (A)	EMI* (V)	EMI* (A+V)
DDD(R)	DVI(R)	DAD(R)	DOO(R)
DDI(R)	DVI(R)	DAI(R)	DOO(R)
DVI(R)	---	DOO(R)	---
VDD(R)	VVI(R)	VAT(R)	VOO(R)
VVI(R)	---	VOO(R)	---
AAI(R)	AOO(R)	---	---
VDI	VVI	VAO	VOO
DDT	DVT	DAT	DOO
DDI/T	DVT	DAT	DOO
DVT	---	DOO	---
VDT	VVT	VAT	VOO
VDI	VVI	VOO	VOO
VVT	---	VOO	---
AAT	AOO	---	---

* EMI = Electromagnetic Interference

15.5 Potentially Harmful Therapeutic and Diagnostic Procedures

Before applying one of the following procedures, a detailed analysis of the advantages and risks should be made. Following the procedures, pacemaker function and stimulation threshold must be checked.

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WARNING

Certain therapeutic and diagnostic procedures may cause undetected damage to a pacemaker, resulting in malfunction or failure at a later time. For a detailed description of these procedures and the appropriate precautions which must be taken, please consult the appropriate section of this technical manual.

CAUTION

Diathermy, transcutaneous electrical nerve stimulation, MRI and electrocautery have been reported to interfere with electrocardiographic monitoring equipment. Cardiac activity during one of these procedures should be confirmed by continuous monitoring of peripheral pulse or blood pressure.

15.5.1 Defibrillation

The circuitry of BIOTRONIK pulse generators is protected against the energy normally induced during defibrillation. Nevertheless, complete protection is not possible; any implanted pulse generator can be damaged by defibrillation procedures. Certain precautions are therefore recommended to minimize the inherent risk of pacemaker operation being adversely affected by defibrillation

- The paddles should be placed anterior-posteriorly or along a line perpendicular to the axis formed by the pacemaker and the implanted lead.
- The energy setting should not be higher than required to achieve defibrillation.
- The distance between the paddles and the pacer/electrode(s) should not be less than 10 cm (4 inches)

Following defibrillation, pacemaker function and stimulation threshold must be checked and monitored for a sufficient time period to verify proper functioning of the pacing system.

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15.5.2 Diathermy

Diathermy therapy is to be avoided for pacemaker patients due to possible heating effects of the pulse generator and at the implant site. If diathermy therapy must be used, it should not be applied in the immediate vicinity of the pulse generator/lead. The patient's peripheral pulse should be monitored continuously during the treatment. Pacemaker function and stimulation threshold must be checked after the therapy.

15.5.3 Radiation

Pulse generator electronics may be damaged by exposure to radiation during radiotherapy. To minimize this risk when using such therapy, the pacemaker should be protected with local radiation shielding. Following radiation exposure, the pacemaker function must be checked and monitored for a sufficient period of time.

15.5.4 Transcutaneous Electrical Nerve Stimulators (TENS)

This therapy is to be avoided for pacemaker patients. If it must be used, the following precautions are recommended:

- The TENS electrodes should be placed as close to each other as possible to reduce current spread.
- The TENS electrodes should be placed as far away from the pulse generator/lead system as possible.
- The cardiac activity and the peripheral pulse should be monitored during the procedure.

For home use, positioning and selection of therapeutic strength should be such that pacemaker operation is not interfered with.

After application of the therapy, pacemaker function and stimulation threshold must be checked.

15.5.5 Magnetic Resonance Imaging (MRI)

MRI should be avoided for pacemaker patients. This diagnostic procedure has been reported to cause movement of the pulse generator within the subcutaneous pocket as well as cause asynchronous pacing, pacemaker pulse inhibition and/or triggering depending on the pacing mode and the interference pattern. Additional risks possibly inherent to the procedure include, but are not limited to, pacemaker malfunction, tissue damage and/or lead displacement.

If the procedure must be used, constant monitoring is recommended, including monitoring the peripheral pulse. Following MRI evaluation, pacemaker function and stimulation threshold must be checked and monitored for a sufficient time period to verify proper functioning of the pacing system.

15.5.6 Lithotripsy

This treatment should be avoided for pacemaker patients since electrical and/or mechanical interference with the pacemaker is possible. During application of extracorporeal lithotripsy, pressure gradients (shock waves) are generated by some devices using spark gap discharges. If this procedure must be used, the greatest possible distance from the point of electrical and mechanical strain should be chosen to minimize a possible influence on the pacemaker. The patient's peripheral pulse should be monitored continuously during the treatment. Following the procedure, the pacemaker function must be checked and monitored for a sufficient time period.

15.5.7 Electrocautery

Electrocautery should never be performed within 15 cm (6 inches) of an implanted pacemaker or lead because of the danger of introducing fibrillatory currents into the heart and/or damaging the pulse generator. Pacing should be asynchronous and above the patient's intrinsic rate to prevent inhibition by interference signals generated by the cautery. When possible, a bipolar electrocautery system should be used.

For transurethral resection of the prostate, it is recommended that the cautery ground plate be placed under the buttocks or around the thigh, but not in the thoracic area where the current pathway could pass through or near the pacing system.

The patient's peripheral pulse should be monitored during the treatment, and the pacing system should be checked for proper operation after the procedure.

16. Technical Data[◇]

16.1 Dromos DR/Dromos DR-A only

Pulse and Control Parameters¹⁾

Mode	DDD* , DDDR , DDI , DDIR , DVI , DVIR , VDD , VDDR , DOO , DOOR , VVI , VVIR , AAI , AAIR , VOO , VOOR , AOO , AOOR , DDI/T , DDT , DVT , VDT , VVT , AAT , VDI , OFF
Dual demand	OFF* , ON [in the modes DDD(R) , VDD(R)]
Lower rate ²⁾	30...(1)...60*...(1)...88...(2)...122...(3)... 140 ppm
Hysteresis ²⁾	OFF* , -6, -12, 18 bpm
Upper rate ²⁾	100, 110, 120, 130, 140, 160* , 185 ppm
UTR response	2:1, WRL (automatic selection)
Dynamic AV delay	low, medium* , high, individual, fixed

Programmable within the following atrial rate ranges at the values specified:

Rate Ranges	LOW	MED	HIGH
below 70 bpm	170 ms	160 ms	150 ms
70 - 90 bpm	160 ms	140 ms	120 ms
91 - 110 bpm	150 ms	120 ms	100 ms
111 - 130 bpm	130 ms	100 ms	75 ms
above 130 bpm	120 ms	75 ms	50 ms

Programming **INDV** allows the user to select specific values within each rate range, thereby customizing the AV delay. Programming **FIXED** AV delay turns off the rate variability

Footnotes follow on page 86.

AV delay	15, 50, 75, 100, 120...(10)...200, 225, 250, 300 ms
AV safety interval	100* , 125, 150 ms
Ventr. blanking time	12, 16, 24* , 32, 40, 48, 56, 72 ms
Magnet effect	Asynchronous* , synchronous (temporary modes only)
Async. magnet effect	In the modes DDD(R), VDD(R), AAI(R), VVI(R), DDT, VDT, AAT, VVT, DOO(R), AOO(R), VOO(R): 10 cycles 90 ppm, thereafter programmed lower rate. In the modes DVI(R), DDI(R), DVT, DDI/T: 90 ppm
Sync. magnet effect	programmed lower rate
Pulse amplitude	(A) 0.1...(0.1)... 4.8* ...(1.2)...9.6 V (V) 0.1...(0.1)... 4.8* ...(1.2)...9.6 V
Pulse width	(A) 0.25, 0.5* , 0.75, 1.0 ms (V) 0.25, 0.5* , 0.75, 1.0 ms
Sensitivity	(A) 0.5...(0.5)... 1.5* ...(0.5)...7.5 mV (V) 0.5...(0.5)... 2.5* ...(0.5)...7.5 mV
Refractory period ³⁾	(A) 200...(25)... 400* ...(25)...775 ms (V) 250, 300* , 350, 400 ms
ARP extension	0* , 50, 100, 150, 200, 250, 300, 350 ms
Lead polarity ⁴⁾	
(A) sense/pace:	unipolar* , bipolar / unipolar* , bipolar
(V) sense/pace:	unipolar* , bipolar / unipolar* , bipolar
Rate limitation ^{2), 5)}	190 ppm

16.2 Dromos SR/Dromos SR-B only

Pulse and Control Parameters¹⁾

Mode	SSIR (VVIR/AAIR); SSI* (VVI/AAI); SOOR (VOOR, AOOR); SOO (VOO/ AOO); SST (VVT/AAT); OFF
Lower rate ²⁾	30...(1)... 60* ...(1)...88...(2)...122...(3)... 140...(5)...180 ppm
Hysteresis ²⁾	OFF* , -6, -12, -18 bpm
Upper rate ²⁾	100, 110, 120, 130, 140, 160* , 185 ppm
Magnet effect	Asynchronous* , synchronous (temporarily programmable)
Async. magnet effect	10 cycles 90 ppm, thereafter programmed lower rate
Sync. magnet effect	programmed lower rate
Pulse amplitude	0.1...(0.1)... 4.8* (1.2) ...9.6 V
Pulse width	0.25, 0.5* , 0.75, 1.0 ms
Sensitivity	(A) 0.4...(0.4)... 2.0* (0.4)...6.0 mV (V) 0.5...(0.5)... 2.5* (0.5)...7.5 mV
Refractory period ³⁾	(V) 250, 300* , 350, 400 ms
Lead polarity ⁴⁾	
sense:	unipolar* , bipolar
pace:	unipolar* , bipolar
Rate limitation ^{2), 5)}	190 ppm

16.3 Dromos DR/DR-A/SR/SR-B

Pulse and Trigger Data at Replacement Indication

Magnet rate	80 ppm for at least 10 cycles immediately after magnet application
Pulse durations	programmed values
Pulse amplitudes	see Figure 22
Sensitivity	programmed values

Rate Adaptation

Sensor gain	1, 1.3, 1.6, 2, 3, 4, 5, 6*, 7, 8, 10, 11, 12, 14, 16, 20, 24, 28, 32, 40
Sensor threshold	LOW, MEAN* , HIGH
Rate increase	SLOW, MEAN* , FAST, VERY FAST
Max. sensor rate ³⁾	Dromos DR: 100, 125* , 150, 170 ppm Dromos SR: 100, 125* , 145, 165 ppm
Rate decrease	VERY SLOW, SLOW, MEAN* , FAST

Additional Functions

Temporary program activation
Threshold test in the range of 0.1 up to 4.8 V
PAC-system for battery voltage independent pulse amplitudes
Analog telemetry with measuring of battery, pulse and lead data
Two channel real time IEGM transmission with markers
Patient data memory
Event counter
Trend monitor
Sensor simulation
Serial number recognition
Position indicator for the programmer head

Programmer

PMS 1000

Materials in Contact with Human Tissue

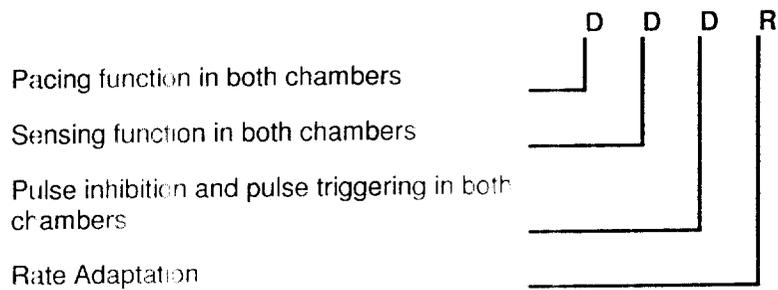
Housing	Titanium
Connector receptacle	Epoxy resin
Sealing plug (DR/SR)	Silicone
Sealing cap (DR-A/SR-B)	Polyoxymethylene
Coating	Silicone

Electrical Data/Battery¹⁾	<u>Dromos DR/DR-A</u>	<u>Dromos SR/SR-B</u>
Pace	unipolar/bipolar	same
Pulse form	biphasic, asymmetric	same
Polarity	cathodic	same
Input impedance	280 k Ω (A); 290 k Ω (V)	290 k Ω
Power source	Li/I ₂	same
Battery manufacturer	Wilson Greatbatch	same
Battery type	WG 8206	same
Battery capacity, nominal ⁶⁾	2.0 Ah	same
Battery voltage at BOS	2.8 V	same
Battery voltage at ERI	2.5 V	same
Battery capacity at ERI	0.15 Ah	same
Current drain at factory settings		
BOS, 100% pacing	35 μ A	25 μ A
BOS, inhibited	18 μ A	16 μ A
Conducting surface (coated)	7 cm ²	same
Conducting shape (coated)	ellipsoidal	same
Circuit	VLSI-CMOS electronics on hybrid	
Nominal service time⁷⁾		
at pulse ampl. 2.4 V	79 months	106 months
at pulse ampl. 4.8 V	60 months	86 months
Expected service time⁸⁾		
at pulse ampl. 2.4 V	105 months	138 months
at pulse ampl. 4.8 V	79 months	113 months
X-Ray Identification	LP	LK
Mechanical Data		
Lead connection	IS-1/5 mm PE	IS-1/6 mm PEC
Size	8.8 x 45 x 51 mm	8.8x41x51 mm
Mass	37 g	35 g
Volume	16 cm ³	15 cm ³

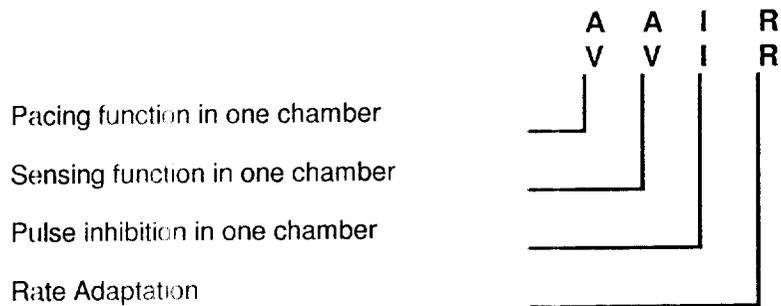
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16.4 NBG Code

The Dromos DR/Dromos DR-A have the NBG-code (Bernstein et al., The NASPE/BPEG Generic Pacemaker Code for Anti-bradyarrhythmia and Adaptive-Rate Pacing and Anti-tachyarrhythmia Devices, PACE 1987; 10: 794-799):



The Dromos SR/Dromos SR-B have the NBG-code (Bernstein, et al., The NASPE/BPEG Generic Pacemaker Code for Anti-bradyarrhythmia and Adaptive-Rate Pacing and Anti-tachyarrhythmia Devices, PACE 1987; 10: 794-799):



Footnotes:

- ◇ Programmability dependent on programmer software utilized.
- * Factory setting
- 1) 37° C, 500 Ohms
- 2) The corresponding intervals t correlate with the rates f by the formula $t = 60,000 / f$ (t in ms, f in ppm).
- 3) In the DDIR, VVIR and VOOR modes, lower maximum sensor rates result than indicated here (partly depending on the selected AV interval). The correct values are indicated by the programmer.
- 4) Dromos DR-A/SR-B polarity is limited to **unipolar** only
- 5) In the event of electronic defect
- 6) Data of the battery manufacturer
- 7) Parameters at factory settings, 100% Stimulation, calculated with the data of the battery manufacturer.
- 8) Calculated with formula: $T = 2740 \times C_{\text{bat}} / (I_{\text{BOS}} + I_{\text{ECS}})$

Specifications subject to modification, revision and improvement.

17. Characteristic Graphs

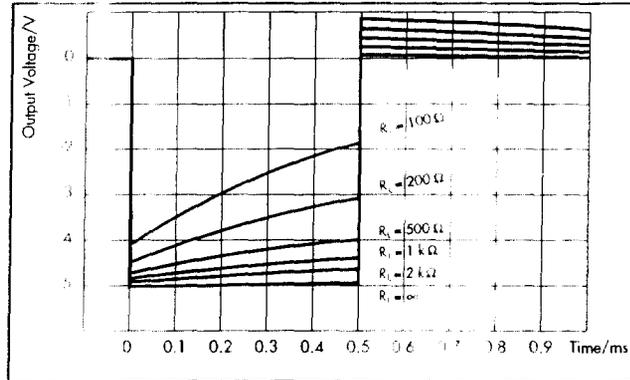


Figure 19. Atrial/ventricular pulse (4.8 V, 0.5 ms) at different loads.

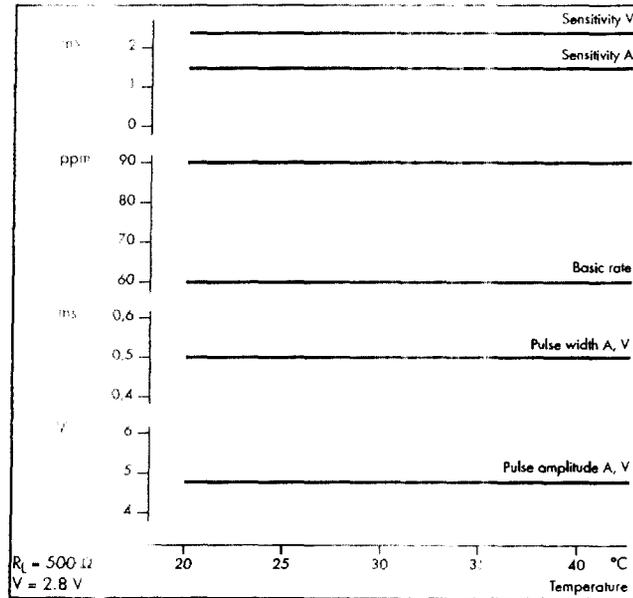


Figure 20. Sensitivity, magnet rate, lower rate, pulse width, and pulse amplitude depending on temperature

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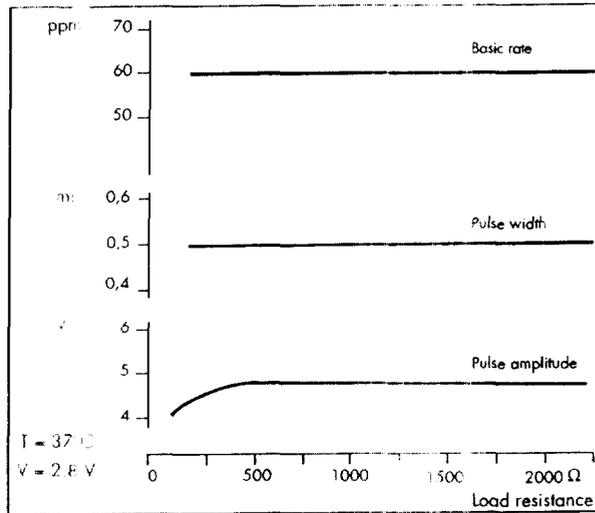


Figure 21. Lower rate, pulse width, and pulse amplitude, depending on load

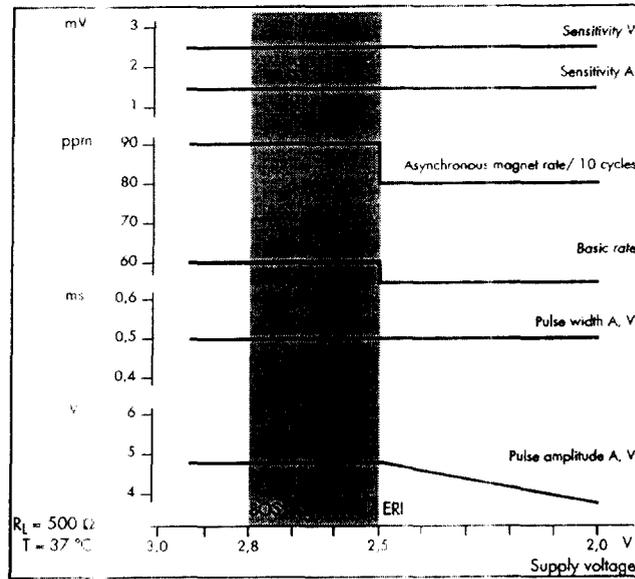


Figure 22. Sensitivity, magnet rate, lower rate, pulse width, and pulse amplitude depending on battery voltage

18. Catalog Information

Type	Catalog Number	Lead Connection
Dromos DR (with silicone coating)	120 851	IS-1
Dromos DR-A (with silicone coating)	120 904	5 mm, PE
Dromos SR (with silicone coating)	120 856	IS-1
Dromos SR-B (with silicone coating)	120 905	6 mm, PEC/ 5 mm, PE with PEH sleeve

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Appendix A

Mode-Specific Indications and Contraindications

Rate Adaptive Pacing

Dromos DR: DDDR, DDIR, DVIR, VDDR, VVIR, AAIR;
Dromos SR: SSIR

Indications for rate adaptive pacing may include but are not limited to the following:

- Patients with chronotropic incompetence who have an anticipated moderate or high level of activity and in whom there is a stable atrial rhythm, and for whom DDD, DDI, DVI, VDD, or VVI pacing is also indicated.
- Patients who have persistent VA conduction (dual-chamber modes)

These indications include but are not limited to sick sinus syndrome and AV block.

The rate adaptive modes of the Dromos DR and Dromos SR pacemakers are contraindicated for patients who are known to develop angina or ischemia at accelerated pacing rates. In addition, the rate adaptive modes are contraindicated in circumstances where the applicable non-rate adaptive mode is noted as contraindicated in the following text.

Dromos DR/DR-A Modes

DDD

*The DDD mode is **clearly indicated** if*

- AV synchrony is needed over a broad range of rates, such as

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1. active or young patients with an adequate increase in atrial rate, and/or
2. significant hemodynamic indication, and/or
3. previous occurrence of pacemaker syndrome or of a reduction in systolic blood pressure of more than 20 mm Hg under ventricular pacing with pacemaker implantation (regardless of any evidence of retrograde VA conduction)

The DDD mode is **conditionally indicated** in the case of

- a complete AV block or of sick sinus syndrome and stable atrial rate, and/or
- proof that simultaneously setting the atrial and ventricular rates can inhibit tachyarrhythmia or if the pacemaker can be set to a pacing mode suited for interrupting arrhythmia.

The DDD mode is **contraindicated** in case of

- frequent or persistent supraventricular tachyarrhythmia, including atrial fibrillation or flutter, and/or
- inadequate intra-atrial complexes that do not permit safe sensing, and/or
- angina pectoris which would be aggravated by increased heart rates.¹

DDI

The DDI mode is useful in all cases in which dual-chamber pacing is necessary, but where intermittent supraventricular arrhythmias frequently occur.

DVI

The DVI mode is **clearly indicated** if

- AV sequential contraction is necessary due to symptomatic bradycardia and slow atrial rate, and/or
- a pacemaker syndrome has already been documented.

¹The ACC/AHA Guidelines cannot replace a study of the relevant specialized literature, especially since the indications and contraindications for using particular pacing modes are subject to constant advances in medical knowledge.

The DVI mode is **conditionally indicated** for

- frequent supraventricular arrhythmia in which a combination of pacing and medication has proved therapeutically effective, and/or
- the presence of a bradycardia-tachycardia syndrome, presuming that setting the atrial rate and the AV interval with or without accompanying medication stops or prevents supraventricular arrhythmia.

The DVI mode is **contraindicated** for

- frequent or persistent supraventricular tachyarrhythmia, including atrial fibrillation or flutter.

VDD

The VDD mode is **clearly indicated** for

- ventricular pacing when adequate atrial rates and adequate intracavitary complexes are present. The indication includes the presence of complete AV block when
 1. the atrial contribution is necessary for hemodynamic optimization, and/or
 2. a pacemaker syndrome has already occurred or is expected.

The VDD mode is **conditionally indicated** for

- patients with normal sinus rhythms and normal AV conduction, but who intermittently need ventricular pacing.

The VDD mode is **contraindicated** for

- frequent or persistent supraventricular tachyarrhythmia, including atrial fibrillation or flutter, and/or
- inadequate intra-atrial complexes that do not permit safe sensing, and/or
- intact retrograde VA conduction¹.

¹The ACC/AHA Guidelines cannot replace a study of the relevant specialized literature, especially since the indications and contraindications for using particular pacing modes are subject to constant advances in medical knowledge.

Dromos DR/DR-A/SR/SR-B Modes

VVI (SSI)

The VVI mode is **clearly indicated** for

- all symptomatic bradyarrhythmias, but particularly if
 1. the atrium does not significantly contribute to the hemodynamics (persistent or paroxysmal atrial flutter or fibrillation, dilated atria).
 2. there are no grounds for development of pacemaker syndrome through loss of the atrial contribution or through negative atrial contribution

The VVI mode is **conditionally indicated** for

- symptomatic bradycardia when the simplicity of the pacing system is of crucial significance due to
 1. senility (for the sole purpose of prolonging life).
 2. incurable illness.
 3. great distance from the follow-up care center to the patient's home.
 4. absence of retrograde VA conduction

The VVI mode is **contraindicated** if

- a pacemaker syndrome is known to exist or if the patient develops particular symptoms during temporary pacing or pacemaker implantation, and/or
- there is a need to maximize the atrial contribution due to
 1. congestive heart failure, and/or
 2. a specific need for ventricular rate adaptation.

AAI (SSI)

The AAI mode is **clearly indicated** for

- symptomatic sino-atrial node dysfunction (sick sinus syndrome), given that adequate AV conduction has been established by an appropriate examination.

The AAI mode is **conditionally indicated** if

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- the hemodynamics of patients with bradycardia and symptomatically reduced cardiac output can be improved by raising the heart rate, given that adequate AV conduction has been established by an appropriate diagnostic examination.

*The AAI mode is **contraindicated** for*

- previously established AV conduction delay or AV block or if diminishing AV conduction has been determined by appropriate tests, and/or
- inadequate intra-atrial complexes that do not permit safe sensing.

Other Modes

(Dual-chamber Modes - Dromos DR/DR-A only)

In addition to the ACC/AHA guidelines, the modes listed above may have further indications due to medical/technical complications such as electromagnetic interference, sensing defects, fracture of the lead(s), detection of myopotentials, muscle stimulation, etc. The same applies to the asynchronous **DOO(R)**, **AOO(R)** and **VOO(R)** pacing modes derived from the above by restricting the sensing functions [SOO(R) mode available with Dromos SR models]. The triggered **DDT**, **DDI/T**, **VDT**, **DVT**, **AAT (SST)** and **VVT (SST)** pacing modes and the **VDI** and **OFF** modes are indicated for diagnostic purposes to assess intrinsic cardiac activity. Use of the **OFF** mode is contraindicated in pacemaker dependent patients.

NOTES:

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BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035-5369
(800) 547-0394 (24-hour)
(503) 635-9936 (FAX)

Manufactured by:

BIOTRONIK GmbH & Co.
Woermannkehre 1
D-12359 Berlin
Germany

M3039-F 10/96

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SWM 1000/C07.C02.U

Software Module for PMS 1000

For programming:

Diplos 05/M 05	Mikros 02
Dromos DR/DR-A	Nanos
Dromos SR/SR-B	Neos 01/02/M 01/LP 01
Gemnos	Pikos LP 01/LP E 01
Gemnos 04/04-A	Pikos 01/01-A/E 01/E 01-B
Gemnos TC 04	Trios M 01/02

BIO **BIOTRONIK**

Technical Manual

CAUTION

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

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Manufactured by
BIOTRONIK GmbH & Co.
Wormannkehre 1
D-12359 Berlin
Germany

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1. General Description

This technical manual describes the functions available with this software and the procedures necessary for interrogating and programming the following BIOTRONIK pulse generators:

SINGLE-CHAMBER	DUAL-CHAMBER
Dromos SR/SR-B	Dromos DR/DR-A
Pikos LP 01/LP E 01	Gemnos TC 04
Pikos 01/01-A/E 01/E 01-B	Gemnos 04/04-A
Nanos	Gemnos
Neos 01/02/M 01/LP 01	Diplos 05/M 05
Trios M 01/02	
Mikros 02	

Please refer to the appropriate technical manual(s) for detailed operation of specific pulse generators. Please refer to the *PMS 1000 Programming and Monitoring System Technical Manual* for a description of the hardware configuration of the programmer.

NOTE:

The programming of pacing modes, parameters and parameter values is determined by the software used for programming and interrogating the pacemaker.

1.1 General Screen Operation

All software functions can be operated through programming windows with the programmer or the keyboard. This section provides a description of screen elements, their operation and activation.

Please refer to the *PMS 1000 Programming and Monitoring System Technical Manual* for further information on basic programmer features, system, ECG and printing functions.

1.1.1 Windows

Each window is designed for the implementation of specific programming or interrogation functions. Windows may contain dialog boxes, parameters, menus, lists, function keys and other screen elements. Each window and its functions are described in subsequent sections.

1.1.2 Lists, Menus, and Dialog Boxes

Lists, menus, and dialog boxes may appear in the open window when a function key or a parameter is activated. These windows and boxes may contain text, menu entries, parameters, and/or value lists. They open automatically when additional information is required. They may also contain messages alerting the user to potential problems, recommended actions, and/or operational status. When several windows or boxes are open, the window or box last opened is the active one.

1.1.3 Parameters

Parameters are elements of a program defining the operation of a pacemaker. Parameters consist of names, values and units of measurement (optional). Selecting a parameter on the screen opens a list of the parameter's programmable values.

A broken line is shown instead of a value for parameters with no application in the selected pacemaker mode. Standard values are displayed if the parameters become programmable due to a change in pacing mode.

Passive Parameters

Passive parameters have either a fixed value or a value automatically set by the software. They cannot be selected in the current window and are identified with an asterisk (*).

Parameter Conflicts

Certain parameter values or combinations of values of different parameters may be blocked from programming for technical or safety reasons. These blocked values are marked ">" or ">>"; indicating a parameter conflict both in the parameter display and in the value window.

Although blocked from permanent programming, parameter conflicts marked ">" can still be programmed temporarily. Parameter conflicts marked ">>" cannot be programmed at all.

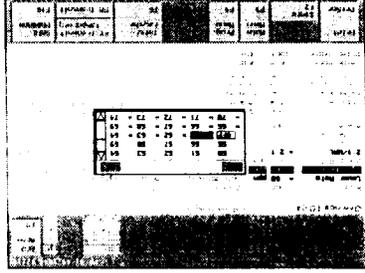


Figure 1. User-programmable parameters, passive parameters and parameter conflicts

1.1.4 Function Keys

Function keys can either trigger a function directly or open a window, list, menu or dialog box. Function keys are activated by touching the corresponding soft key displayed in the window on the attached external PC keyboard. Each soft key contains a descriptive name of its function.

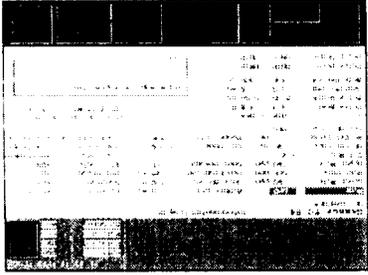


Figure 2. Main Function Keys

A general description of each function key follows. Window specific functions are described in Sections 5 and 6.

Print/Scr Print

This function key only appears in windows with a print function. Activation of this key immediately prints the relevant data from the open window or stores the data in a print file.

NOTE:

Continuous ECG cannot be printed using this key.

F2 Store

This function key only appears in windows or menus with a storage function. This key has a different function in each window.

Please refer to Sections 5 and 6 for further details.

F3 Main Menu

This function key appears in all windows and menus. Activation of this key opens a menu of all the main functions of the selected pacemaker. This main menu is identical in all windows with the exception that the current window does not appear as an option in the menu.

F4, F5

These keys only appear in windows where submenus are necessary. The keys' function and descriptive names vary according to the window in which they appear.

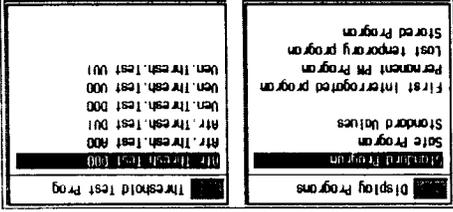


Figure 3. Display Program Submenu, Threshold Test
Submenu

F6 Interrogate

Activation of this function key sends a command to the programming head to interrogate the pacemaker. This key has somewhat different functions in each window as specified in Sections 5 and 6.

F7

This function key only appears in those windows with temporary pacemaker programming capability. Its function and descriptive name vary according to the window in which it appears and are described in Sections 5 and 6.

F8 Transmit

This key only appears in the Program window. Activation of this key transmits the displayed parameters as a permanent program.

F9 ECG Menu

Activation of this function key opens a selection window listing all of the functions used to control the display and printing of ECGs and IEGMs.

F9 Stop ECG Print

This function key only appears if the ECG window is closed while an ECG (and/or an IEGM) is being printed. Activation of this key terminates ECG (IEGM) printing.

F10 Safe Program

This function key is always present. Activation of this key transmits the safe program as a permanent program.

Other function keys may also appear in an open window. They are described in Sections 6 and 7.

1.1.5 Screen Element Activation

Elements on the screen (parameters, values, menu entries, function keys, etc.) are activated by touching them on the screen with the programmer pen or by using an external PC keyboard.

Programmer instructions in this manual are enclosed in boxes. Separate pen and keyboard commands are only given when necessary. The two screen element activation methods are denoted in this manual as follows:

- Actions using the programmer pen.
- Actions using an external PC keyboard

2. Warnings

Battery/Lead Data Transmission

Battery/lead data collection and transmission may take up to 4 seconds. The pacemaker cannot be reprogrammed during this time even if the **Save Program** key is pressed. Remove the programming head immediately to restore the permanent program.

IEGM Transmission

The pacemaker cannot be interrogated or programmed during IEGM transmission. Remove the programming head to terminate IEGM transmission and restore the permanent program.

Lead Polarity (Gemnos, Pikos, and Eromas families)

Polarity Programming. The pacing or sensing programming for each chamber must be compatible with the polarity of its implanted lead. Unipolar pacing and sensing functions must be programmed for all unipolar leads. Failure to program correctly can result in exit block for the chamber with a unipolar lead. Verify that bipolar leads have been implanted in any chamber that is programmed in the bipolar configuration.

Patient Data Memory. If the lead polarity setting within the Patient Data Memory has been set to bipolar, the polarity of the corresponding implanted lead(s) must also be bipolar.

3. Cautions

High Pulse Amplitude [Gemnos 04, 04-A, TC 04; Pikos]

Programming of pulse amplitudes higher than 4.8 V in combination with long pulse widths and/or high lower rates can lead to premature activation of the replacement indicator. [Dromos] If a pulse amplitude of 7.2 V or higher is programmed and high pacing rates are reached, output amplitudes may differ from programmed values.

Threshold Test

It is strongly recommended that a minimum of a 2:1 safety margin be permanently programmed whenever capture thresholds are assessed

Monitor the ECG display closely with pacemaker-dependent patients. Terminate the test immediately upon loss of capture

Temporary Sensing Test [Gemnos 04, 04-A, TC 04; Pikos]

Asynchronous pacing occurs after sensing threshold has been reached in the above pacemakers featuring the temporary sensing test.

4. General Program Functions

4.1 Implant List

The Implant List window appears on the programmer screen immediately after completion of the self-test. It contains a list of the pacemakers programmable with this software. The complete list of pacemakers contained in this software version is listed in Section 1.

The Implant List window provides access to the Program window in two ways: First, selection of a pacemaker from the implant list will open the Program window with the selected pacemaker's Standard Program. Second, holding the programming head over a pacemaker initiates an automatic interrogation and identification sequence. The Program window then opens and displays the pacemaker's permanent program.

4.2 Identification and Interrogation of the Pacemaker

All BIOTRONIK pacemakers programmable with this software are capable of bidirectional telemetry—that is, they can be both interrogated and programmed.

The identification and interrogation of an implanted pacemaker can be performed manually using the **F6 Interrogate** function key or automatically as described below.

4.2.1 Automatic Positioning Aid and Interrogation

A small light on the programming head indicates telemetry contact with the pacemaker. The indication differs for various pacemaker groups:

- For Dromos DR/SR, Gemnos 04/04-A/TC 04 and Pikos, contact with the pacemaker is indicated by regular, high frequency flashing of the light.

- The positioning aid function is not available with the Dipsos 05/M 05.
- For all other pacemakers, contact is indicated by the light flashing in time with the programmed lower rate.

To identify and interrogate the pacemaker automatically:

1. Position the programming head over the pacemaker and move it until the light on the programming head indicates contact with the pacemaker.

After contact is made, the pacemaker is automatically identified and its program is interrogated.

NOTES:

If the programming head is on the border of the contact area, the light blinks irregularly. Move the programming head over the pacemaker until the light on the programming head indicates contact. Interrogate the pacemaker or activate the desired programmer function.

- If the positioning aid does not activate automatically when changing from one group of pacemakers to another (due to the technical differences between the various pacemakers), interrogate the pacemaker manually using the **F6 Interrogate** key.
- It is recommended to start a follow-up examination on a new patient from the pacemaker list.

5. Pacemaker-Specific Program Functions

5.1 Setting and Transmitting a Temporary Program

[Promos DR, SR; Gemnos, 04, 04-A, TC 04; Pikos]

A temporary program is a transmitted set of parameters that remains active only as long as the read switch is closed (i.e. while the programming head is in contact). The original permanent program is reactivated as soon as the programming head is removed, providing the maximum possible degree of patient safety.

All parameters available in the Program window can be transmitted as a temporary program provided there are no parameter conflicts marked ">" Parameters marked ">" can be programmed temporarily.

To transmit a temporary program:

1. Position the programming head over the pacemaker.
2. Activate the **F7 Transmit Temporary** function key.

The temporary program remains active as long as the programming head is in contact with the pacemaker.

NOTES:

To retain the pacemaker's sensing function while SYNC (synchronous). Otherwise, asynchronous pacing (without sensing) will occur while the programming head is in position.

- Temporarily programmable values may vary from software versions available with previous programmer models.

5.2 Dynamic AV Delay - Non-Rate Adaptive Pacemakers

[Gemnos 04, 04-A, TC 04]

The Dynamic AV Delay allows the adjustment of the AV delay after intrinsic events for five separate ranges of atrial rates. The Dynamic AV Delay provides the ability to differentiate AV delays depending on the detected atrial rate.

NOTE:

Either a Dynamic AV Delay or an AV Delay sense must be programmed for proper pacemaker function.

Four predetermined settings (off, low, medium, high) are available. AV delays can also be individualized within each of the rate ranges. A Dynamic AV Delay can only be set in conjunction with DDD, VDD, VAT pacing modes.

To open the **Dynamic AV Delay** window:

1. Select the **Dyn. AV Delay** parameter.

A window opens displaying the preset AV delays for the five rate ranges and keys for the corresponding predetermined settings. The key with the current setting of the Dynamic AV Delay is activated.

To program predetermined settings:

1. Select the desired predetermined setting (e.g., 2 km) from the opened Dynamic AV Delay window.
2. Select the 9 OK function key.

The value selected in the window appears in the displayed program. (Close the window without selecting the 9 OK key to retain the previous value.)

5.3.2 Pacemaker Mode Without Rate Adaption

An AV delay for stimulation and a fixed AV delay or a rate-dependent AV delay for detection can be selected through the Dynamic AV Delay selection window.

To program individual dynamic AV delays for stimulation and detection:

1. Select the desired rate range from the opened Dynamic AV Delay window.
2. Select the desired AV delay value from the list.

Repeat steps 1 and 2 for the desired rate ranges.

The AV delay value window in the given rate range closes and the selected value appears in the Dynamic AV Delay window for each rate range. If the list of rate-dependent AV delays differs from the predetermined settings, an additional key marked **5 Indvtd** appears in the window.

3. Select the **9 OK** function key.

The list of AV delays is entered and the value **INDV** appears (Close the window without touching the **9 OK** key to retain the previous value.)

To program a **fixed AV delay** for stimulation and detection:

1. Select the **1 fixed** function key.
2. Open the **All Rates** selection window and select a value.
3. Select the **9 OK** function key.

The selected AV delay for all rates is entered and the value **FIXED** appears. (Close the window without touching the **9 OK** key to retain the previous value.)

To program an AV delay for stimulation and a predetermined setting for AV delay for detection:

1. Open the **Dynamic AV Delay** value window.
2. Select the **Lower Rate** parameter setting.
3. Select the desired AV delay value from the list.
4. Select the desired predetermined setting (e.g., **3 maximum**) from the opened Dynamic AV Delay window.
5. Select the **9 OK** function key.

The selected AV delay for the lower rate and for detected rates exceeding the lower rate are entered. The display window will show the selected predetermined setting (e.g., **MEP**). (Close the window without touching the **9 OK** key to retain the previous value.)

To program an AV delay for stimulation and a single independent AV Delay for detection:

1. Open the **Dynamic AV Delay** value window.
2. Select the **1 fixed** key.
3. Select **Lower Rate**.
4. Select the desired AV delay value.
5. Select **>Lower Rate**.
6. Select the desired AV delay value.
7. Select the **9 OK** function key.

The selected AV delays for the lower rate and for detected rates exceeding the lower rate are now programmed. The value **FIXED** is displayed. (Close the window without touching the **9 OK** key to retain the previous value.)

To program an AV delay for stimulation and a patient-specific set of AV delay values for detection:

1. Open the **Dynamic AV Delay** value window; at **Lower Rate** and select the desired value.
2. Select **Lower Rate**; then select the desired value.
3. Select the desired predetermined setting (e.g., 3 medium).
4. Select the desired rate range.
5. Select the desired value for the rate range.
6. Repeat steps 2 and 3 for the desired rate ranges.

The value window for the AV delay in the given rate range closes and the selected value appears in the **Dynamic AV Delay** window. If the list of rate-dependent AV delays differs from the set values, a key marked **5 (mV)** appears in the window.

The selected AV delay for the lower rate and for detected rates exceeding the lower rate are entered into the displayed program. The value **INDV** is displayed. (Close the window without touching the **9 OK** key to retain the previous value.)

5.4 Programming High Pulse Amplitudes

[Gemnos 04, 04-A, TC 04; Pikos]

When the replacement indication appears at a high amplitude setting, the pacemaker must be reprogrammed to a lower pulse amplitude. The pacemaker should be interrogated immediately to see if the replacement indication is still active.

CAUTION

Programming of pulse amplitudes higher than 4.8 V in combination with long pulse widths and/or high lower rates can lead to premature activation of the replacement indicator.

NOTE: Pacemaker reprogramming to lower amplitudes should only be performed if an adequate safety margin above the measured threshold can be maintained.

To verify replacement indication:

1. Reprogram the pacemaker with a lower pulse amplitude (4.8 V maximum).
2. Move the programming head at least 15 cm away from the pacemaker for at least 10 seconds.
3. Reposition the programming head, interrogate the pacemaker and reevaluate the replacement indicator.

[Dromos DR, SR]

CAUTION

If a pulse amplitude of 7.2 V or higher is programmed and high pacing rates are reached, output amplitudes may differ from programmed values.

5.5 Lead Polarity Selection

[Dromos DR, SR; Gemnos, 04, TC 04; Pikos 01, E01, LP 01, LP E01]

These pacemakers can be connected to both unipolar and bipolar (S-T leads. If bipolar leads are connected, either a bipolar or a unipolar lead configuration can be programmed in the pacemaker.

To program bipolar lead polarity:

1. Interrogate the pacemaker.
2. Open the **Polar.Pace** or **Polar.Sense** value window and select **BIPL**.

The value window will close and the selected value appears with a conflict symbol. A release code window containing additional information opens automatically.

To confirm bipolar lead configuration:

1. Select **1 Release BIPL**.

The conflict symbol next to the parameter value disappears when the release code has been entered.

To cancel bipolar lead configuration

1. Close the release code window
2. Reopen the **Polar.Pace** or **Polar.Sense** value window and select **UNIP**.

NOTE:
The bipolar lead configuration does not need release if Patient Data Memory is programmed to **BIPL**.

WARNING

The pacing and sensing programming for each chamber must be compatible with the polarity of its implanted lead.

Unipolar pacing and sensing functions must be programmed for all unipolar leads. Failure to program correctly can result in exit block for the chamber with a unipolar lead.

Verify that bipolar leads have been implanted in any chamber that is programmed in the bipolar configuration.

in order to prevent accidental programming of a bipolar configuration for a unipolar implanted lead, a dialog box appears requiring a second confirmation (see Fig. 5).

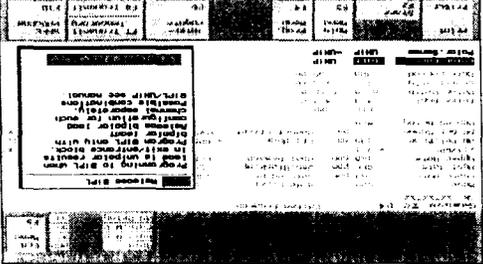


Figure 5. Lead Polarity

5.6 Activating The Marker Function

[Pikos; Gemmos 04, 04-A, TC 04]

These pacemakers can transmit both analog and digital event markers via the programming head to the programmer.

1. The following digitally-coded event markers are transmitted during certain temporary programs (see Figures 6 and 7).

- Faced events (A_p and V_p)
 - Sensed events (A_s and V_s)
2. Available only during an IEGM transmission, the following analog markers are displayed for each channel (see Figures 6 and 7):
- Paced events (A_p and V_p)
 - Sensed events outside of the refractory period (A_s and V_s)
 - Sensed events within the refractory period (unused A_s and unused V_s)

All event markers are displayed in the area above the ECG display and can be printed simultaneously with the ECG/EGM. These markers are also transmitted via the programmer's ECG output and can thus be documented on an external ECG recorder at the same time as the surface ECG.

NOTE:
Some pacemakers of the Pikos and Gemmos series do not contain the function of digitally coded event markers.

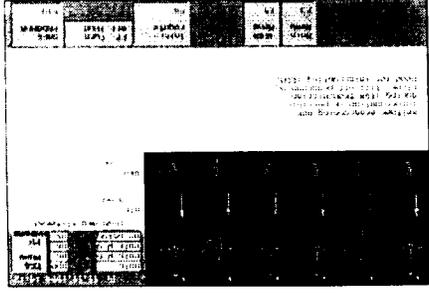


Figure 6. Marker Telemetry

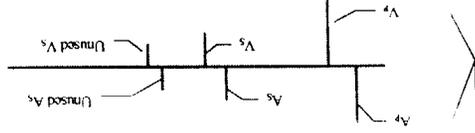


Figure 7. Marker Descriptions

5.7 Restricted Programmability For Short AV Delays

[Diplois 05, M 05]

Pacing pulses may interfere with the identification string following the transmission of the pacemaker program when very short AV delays (15 ms or 50 ms) are programmed. A special function with restricted programmability enables these short AV delays to be transmitted without pacemaker identification string interrogation. This special function must be confirmed in a release code window.

To program a short AV delay

1. Open the AV Delay value window and select a short AV delay of 15 ms or 50 ms.

The value window will close and the selected value will appear. An AV delay confirmation window opens automatically.

To release the special programming function for short AV

delays:

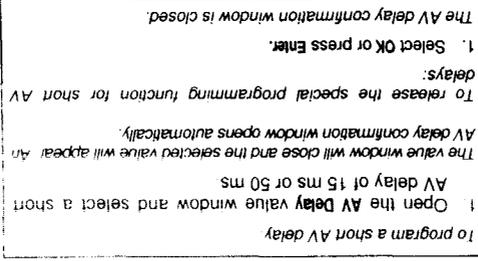
1. Select OK or press Enter.

The AV delay confirmation window is closed.

5.8 Sensor Simulation

[Dromos DR, DR-A, SR, SR-B]

The sensor function can be simulated when rate adaptive pacing is turned off. The simulation results can be stored and evaluated with the Trend Monitor.



To activate (deactivate) sensor simulation:

1. Open Mode value window and select an applicable mode without rate adaption.

2. Open Sensor Simul. value window and select ON (OFF).

3. Open the value windows of the rate-adaptive parameters and select the desired values.

4. Transmit this program to the pacemaker (F8).

Sensor simulation is activated (deactivated).

To activate trend monitor:

1. Open the Main Menu and select the item Trend Monitor

2. Open the value window Count Event and select Simul.

3. Select the other trend monitor parameters according to the desired protocol.

4. Select F5 Start Trend (again) to start the trend recording.

The trend monitor records the sensor reactions which correspond to the patient's activities. Interrogate the trend monitor after completion of the desired protocol.

To interrogate the trend monitor:

1. Open the Main Menu

2. Select the item Trend Monitor.

3. Interrogate trend monitor (F8).

The Trend Monitor displays the reaction the sensor would have shown in a rate-adaptive pacing mode. If the results don't meet patient needs, the simulation can be repeated with different rate-adaptive parameter values. See Section 6.6 for further details on trend monitor operation.

6. Pacemaker-Specific Follow-Up Functions

6.1 Threshold Test

[Dromos DR, SR; Gernmos 04, TC 04; Pikos]

A rapid estimation or an exact determination of the pacing capture threshold can be accomplished with the temporary variable program sequence described below.

6.1.1 Window Description

Five additional smaller ECG fields below the real-time ECG permit side-by-side comparisons of ECGs associated with different test amplitudes. Each field can temporarily store an ECG reading and its corresponding test amplitude. When active the field is refreshed after each pulse as long as the test amplitude is left unchanged.

The left field contains the reference ECG resulting from the initial test amplitude setting. When the test amplitude is changed from the initial setting, the reference ECG field is frozen and the ECG field immediately to the right becomes active. The reference ECG field remains frozen with its corresponding test amplitude throughout the duration of the threshold test for comparison purposes. From this point on, only the four fields to the right of the initial ECG field are used.

Each time the test amplitude is changed, the currently active field freezes and the field immediately to the right begins to display the ECG resulting from the new test amplitude selection. The older field is always on the left side, next to the reference ECG field. Threshold test results can be printed after test completion using the **Print** key.

6.1.2 Test Procedures

To select a Threshold Test:

1. Open the Main Menu and select **Threshold Test**.

A window appears displaying a selection of mode-specific threshold tests.

2. Select a mode-specific threshold test.

The Threshold Test window appears showing the standard settings for the selected test. The test may be started immediately or the test parameters can be modified.

All parameters in the Threshold Test window except mode may be changed before the test is started. After the test program has been modified, the values for **Lower Rate** and **Resolution** can be stored permanently in the programmer. These settings will appear as the standard values in subsequent threshold tests.

To store Threshold Test settings:

1. Select the **F2 Store** function key.

A window opens showing the programmable parameter settings.

2. Adjust to the desired settings.
3. Select the **9 OK** function key.

To cancel without saving the adjusted settings, select **Esc**.

In the standard setting, continuous ECG and corresponding amplitude/pulse width values are automatically printed when the threshold test starts.

- To disable or (enable) the Automatic Test Protocol:
1. Open the Main Menu.
 2. Open the System Functions window.
 3. Open the Test Protocol value window.
 4. Select OFF (ON) and close open windows.

During the threshold test, the displayed parameters are transmitted to the pacemaker as a temporary program. The reference ECG field displays the ECG resulting from the initial test amplitude. (If Test Protocol is enabled, the ECG is printed throughout the test.)

CAUTION
Monitor the ECG display closely with pacemaker-dependent patients. Terminate the test immediately upon loss of capture.

- To perform the threshold test:
1. Select the F7 Start Test function key:
The displayed program is immediately transmitted to the pacemaker as a temporary program with the selected amplitude.
 2. Select a new test amplitude value from the list on the right.
 3. Stop the test by moving the programming head at least 15 cm away from pacemaker or by selecting the F7 Stop Test function key.
- The pacemaker automatically returns to the permanent program.

(The test terminates automatically when the programming head is moved at least 15 cm away from the pacemaker.)

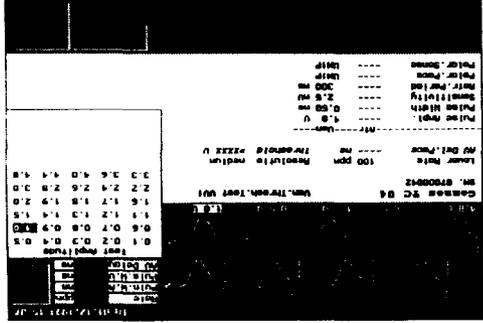


Figure 8. Threshold Test

6.1.3 Reading And Entering The Threshold

The threshold value is obtained from either the ECG printout or the ECG fields on the screen.

To enter the threshold value:

1. Open the value window for Threshold.
 2. Select the measured value for the capture threshold.
- The selected value is accepted and the window closes.

The new capture threshold value can be printed with the five ECG fields.

CAUTION

At least a minimum of a 2:1 safety margin should be permanently programmed any time capture thresholds are assessed.

6.2 Temporary Sensing Test

[Pikos; Gemnos, 04, 04-A, TC 04]

A rapid estimation or an exact determination of the sensing threshold can be accomplished with the variable program sequence described below.

The following test parameters can be programmed:

- test rate (**Lower Rate**)
- number of sensed events per step (**Sense/Step**)
- change in sensitivity value (**Step Size**)

Once the test is started, sensitivity reduction only takes place in the previously selected channel. The sensitivity programmable value is increased according to the user's specifications until the maximum value has been reached or the sensing test is terminated.

NOTE: Certain pacemakers of the Pikos and Gemnos 04 series do not feature an automatic sensing test. The sensing value can be determined safely with manual step-by-step sensitivity reduction and temporary program transmission. The IEGM may also be transmitted to achieve a safe interpretation of events and an exact measurement of the P- and R-wave amplitude.

CAUTION

Asynchronous pacing occurs after sensing threshold has been reached in the above pacemakers featuring the temporary sensing test.

6.2.1 Test Procedures

To select a sensing test:

1. Open the Main Menu and select Sensing Test.

A window appears displaying a selection of mode-specific sensing tests.

2. Select a mode-specific sensing test.

The Sensing Test window appears showing the standard settings for the selected test. The test may be started immediately or the test parameters can be modified.

All parameters in the Sensing Test window except mode may be changed before the test is started. After the test program has been modified, the values for Lower Rate, Sense/Step and Step Size can be stored permanently in the programmer. These settings will appear as the standard values in subsequent sensing tests.

To store sensing test settings:

1. Select the F2 Store function key.

A window opens showing the programmable parameter settings.

2. Adjust to the desired settings.

3. Confirm the modified settings.

4. Close the window by touching the 9 OK function key.

(To cancel without saving the adjusted settings, select Esc.)

In the standard setting, continuous ECG, corresponding event markers and sensitivity values are automatically printed when the sensing test starts.

- To disable or (enable) the automatic test protocol:
1. Open the **Main Menu**.
 2. Open the **System Functions** window.
 3. Open the **Test Protocol** value window.
 4. Select **OFF (ON)** and close open windows.

During the sensing test, the displayed parameters are transmitted to the pacemaker as a temporary program. This program remains active until at least two consecutive sensed events have been detected by the pacemaker. Then additional temporary programs are sequentially transmitted to the pacemaker, with a step-by-step reduction in sensitivity.

The ECG is displayed automatically with event markers. (If **Test Protocol** is enabled, the ECG is printed throughout the test.)

To perform the sensing test:

1. Select **F7 Start Test** function key.

The displayed program is immediately transmitted to the pacemaker as a temporary program with the selected sensitivity.

To stop the test:

1. Move programming head at least 15 cm away from pacemaker select the **F7 Stop Test** function key

The pacemaker automatically returns to the permanent program.

The test terminates automatically when the maximum sensitivity value has been reached or the programming head is moved at least 15 cm away from the pacemaker.

NOTE:

An increase in the sensitivity value corresponds to a reduction in sensitivity (i.e., the greatest value corresponds to the lowest sensitivity).

6.2.2 Reading And Entering The Sensing Threshold

When the sensing test is terminated, the sensitivity value at the time the test was terminated is displayed on the screen (**Sens.Stp**). Since loss of sensing may have occurred prior to the termination of the test, this value does not necessarily correspond to the measured sensing threshold.

The exact value can be obtained from the ECG printout. Record the sensitivity value of the marker above the last detected intrinsic event.

- To enter a value for the sensing threshold:
1. Open the value window for **Threshold**.
 2. Select the measured value for the sensing threshold.
- The selected value is accepted and the window closes.

The new sensing threshold value can be printed with the **Print** key.

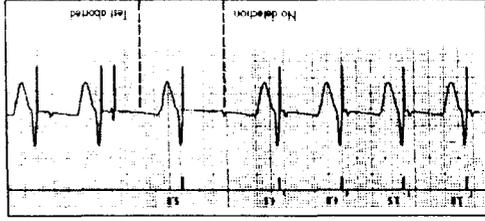


Figure 9. Atrial Sensing Test (VDD)

6.3 Battery/Lead Telemetry

[Dromos DR, SR; Gemnos 04, 04-A, TC 04; Pikos]

Direct voltage and current readings transmitted from the pacemaker via telemetry to the programmer provide instant data on pacing system electrical status.

The following data are available in the Battery/Lead Telemetry window:

Parameter	Unit of Measurement
Battery voltage	V
Battery current	µA
Battery impedance	kOhms
Pulse voltage	V
Pulse current	mA
Pulse energy	µJ
Pulse charge	µC
Lead impedance	Ohms

Values outside the measurement range are represented by dashes. The measurement tolerance can be obtained from the respective pacemaker technical manual.

WARNING

Battery/lead data collection and transmission may take up to 4 seconds. The pacemaker cannot be reprogrammed during this time even if the Safe Program key is pressed. Remove the programming head immediately to restore the permanent program.

To obtain battery and lead data:

1. Open the Main Menu.
2. Select Battery/Lead Telemetry.

The parameters displayed in the open window are automatically programmed temporarily. Voltage and current measurements start immediately for the temporary program and in approximately four seconds the data appear in the Battery/Lead Telemetry window.

To repeat the measurement:

1. Select the F7 Start Measure function key.

NOTES:

- Battery and lead measurements are only possible with pulse amplitudes < 5.0 V
- The Pkios LP 01 transmits the lead impedance readings only

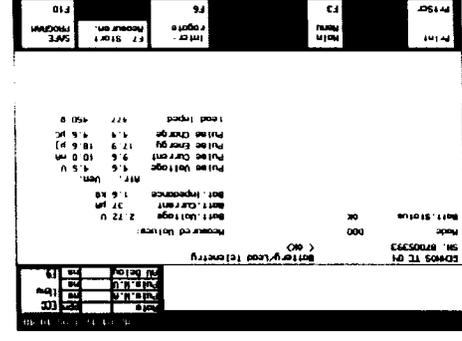


Figure 10. Battery and Lead Telemetry

6.4 Intracardiac Electrogram (IEGM)

[Dromos DR, SR; Gemnos 04, 04-A, TC 04; Pkios]

These pacemakers can record the IEGM in the atrium and the ventricle via pacemaker leads and transmit the results to the programmer via the programming head. This data can be sent as unfiltered IEGM directly to the programmer or as filtered IEGM after selective amplification of typical cardiac-generated frequencies (~5-75Hz).

The pacemaker cannot be interrogated or programmed during IEGM transmission. The ECG Menu is the only functional menu during in the IEGM window. The programming head must be removed prior to use of any other functions.

The following analog event markers associated with these tracings are transmitted to the programmer simultaneously:

- Pace event
- Sense event outside the refractory period
- Sense event inside the refractory period (only transmitted in conjunction with IEGM)

WARNING

The pacemaker cannot be interrogated or programmed during IEGM transmission. Remove the programming head to terminate IEGM transmission and restore the permanent program.

<p>To start an IEGM transmission:</p> <ol style="list-style-type: none"> 1. Open the Main Menu and select IEGM. 2. Select the desired option. <p>A list of IEGMs appears.</p> <p>The displayed program is transmitted as a temporary program in synchronous magnet operation. The IEGM display appears and transmission starts automatically.</p> <p>If transmission is unsuccessful or pacemaker communication is interrupted, the on-screen IEGM will freeze and an error message will appear. Note the information in the error message. Select F7 to terminate IEGM transmission again.</p>	<p>To terminate IEGM Transmission</p> <ol style="list-style-type: none"> 1. Move the programming head at least 15 cm away from the pacemaker. <p>The permanent program is restored. Upon return to the program screen, the temporary program transmitted at the onset of IEGM transmission will be displayed.</p>
<p>To transmit the safe program:</p> <ol style="list-style-type: none"> 1. Briefly move the programming head at least 15 cm away from the pacemaker to interrupt IEGM transmission. 2. Replace the programming head over the pacemaker. 3. Then press the F10 Safe Program key. 	

Pacemaker sensitivity and IEGM amplitude are inversely related. That is, an increase in the **Sensitivity** parameter (mV) decreases the size of the IEGM image. Conversely, a decrease in the mV setting of the Sensitivity parameter increases the apparent size of the IEGM.

6.4.1 Filtered IEGM Sensitivity

For an accurate measurement of P-wave or R-wave amplitude, the maximum signal amplitude must be less than the calibration signal. Different sensitivities can be programmed to alter the size of the calibration signal.

Sensitivity values should be selected so that the entire waveform fits within the IEGM display.

NOTE:

The range of the maximum signal amplitude is represented by a calibration signal on the IEGM printout and corresponds to twice the programmed sensitivity.

6.4.2 IEGM Program Transmission

The parameters displayed in the Program window are transmitted upon IEGM selection. These parameters do not need to be transmitted as a temporary or a permanent program to the pacemaker. They remain active only during IEGM transmission. Once the IEGM transmission is completed, the permanent program is restored.

To set the sensitivity for the filtered IEGM:

1. Open the **Main Menu** and select **Program**.
2. Select **Sensitivity**.
3. Select the desired value.
4. Select **F7 Transmit Temporary** or **F8 Transmit** to transmit the program to the pacemaker.

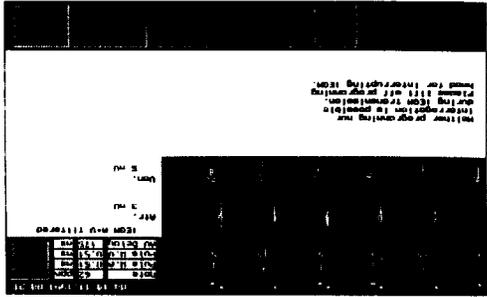


Figure 11. IEGM Display (filtered IEGM)

6.5 Event Counter

[Dromos DR, SR; Gemnos TC 04]

The event counter records sensed and paced events in the atrium and ventricle as well as ventricular extrasystoles. In addition to counting the number of events of each type, each event type proportion is displayed as a percentage of all the recorded events in each chamber.

6.5.1 Counter Capacity

Each counter can store a maximum of 16,777,215 events. If any single counter exceeds the maximum number of events, all counters stop at their last value. This capacity correlates to a six-month time period at an average heart rate of 60 bpm. The counter is momentarily deactivated to prevent inaccurate counting caused by asynchronous pacing when the programming head (or magnet) is over the pacemaker.

NOTE: Check the setup of the programmer before the event counter is activated to ensure that the settings for time and date are correct. If the settings are not correct, reset them using the procedure outlined in the *PMS 1000 Programming and Monitoring System Technical Manual*.

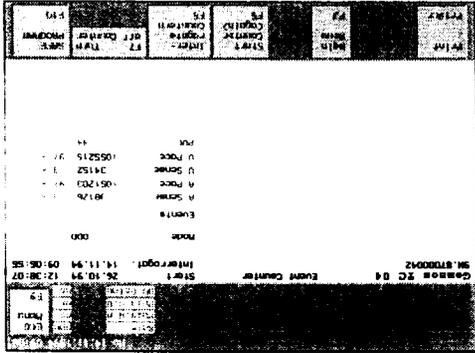


Figure 12. Event Counter

6.5.2 Counter Operation

To activate the event counter:

1. Open the Main Menu.
2. Select Event Counter.
3. The Event Counter window appears.

If the counter is already active, the pacemaker is automatically interrogated and the event results displayed. (If interrogation is unsuccessful, an error message appears. Note the advice given in the error message, and interrogate the Event Counter again by selecting **Reinterrogate**.)

<p>To enable or reset the counter:</p> <ol style="list-style-type: none"> 1. Select the F5 Start Counter (again) function key. <p>The counter is activated (or reset). Counting will begin when the programming head is moved at least 15 cm away from the pacemaker.</p>	<p>To inactivate the event counter:</p> <ol style="list-style-type: none"> 1. Select the F7 Turn off Counter function key. <p>The event counter is inactivated.</p>
--	--

NOTE:

The event counter inactivates automatically when the replacement indication has been reached

6.6 Trend Monitor

[Dromos DR, SR; Gemnos TC 04]

The trend monitor counts and stores events over a fixed time period. Interrogation of the trend monitor after data collection provides histograms showing the distribution of the selected events within the selected time period. Two different events can be tracked simultaneously. Analysis of these trends can be used to optimize pacemaker settings. Trend monitor results and analyses can be printed from any window using the **Print PMSor** function key.

6.6.1 Recording Period

The recording period is divided into 64 time windows in which the selected events are counted and from which the average per minute is calculated. A maximum of 256 events can be counted in each time window.

The trend monitor session is defined by the Counter Run (total recording period) and Time Window (time window width) parameters where:

$$\frac{\text{Total Recording Period}}{\text{Time Window Width}} = 64$$

Because the number of time windows is fixed, adjusting either one of these parameters necessarily modifies the other. For example, time windows of 10 seconds and 60 minutes result in recording periods of 640 seconds and 64 hours, respectively. Similarly, a 5 hour recording period will result in time window width of 5 minutes. Longer durations of Counter Run (more events averaged in each time window) may conceal brief increases or decreases in heart rate.

The parameters can be selected to monitor a wide range of clinical scenarios. For instance, short trends are best utilized to evaluate the patient's chronotropic status during a specific exercise protocol. On the other hand, a long trend can be used to provide a cardiac profile over an extended time period.

NOTE:

To prevent inaccurate counting caused by asynchronous pacing, the trend monitor is momentarily deactivated while the programming head (or magnet) is over the pacemaker.

6.6.2 Trends

Count Events

The pacemaker can count and store the following trend events: **A-Sense**, atrial sense; **A-Pace**, atrial pace; **A-Events**, the sum of A-Sense and A-Pace; **V-Sense**, ventricular sense; **V-Pace**, ventricular pace; and **V-Events**, the sum of V-Sense and V-Pace.

Trends = 2

The pacemaker can store two independent trends (Trends = 2) at the same time.

If the time scale is identical, the trends can be added to or subtracted from one another. For example, the trends for A-

Events and A-Face may be used to calculate the trend for A-Sense as well.

Trends = 1

The recording periods can be set to run consecutively so that one trend with 128 time windows for a maximum time period of 128 hours can be recorded.

6.6.3 Counter Mode

The two trends can be recorded independently of each other, either in the fixed or rolling mode (Counter Mode). In the fixed mode, the trend is retained after the recording period has elapsed. In the rolling mode, on the other hand, the recorded value in the oldest time window is overwritten once the recording period is completed, so that the trend for the last time interval prior to interrogation is always recorded.

NOTE:

Check the setup of the programmer before trend monitor is activated to ensure that time and date settings are correct. If the settings are not correct, reset them using the procedure outlined in the *PMS 1000 Programming and Monitoring System Technical Manual*.

6.6.4 Trend Monitor Operation

To activate or reset the trend monitor:

1. Open the Main Menu.
2. Select Trend Monitor.

The Trend Monitor window appears.

If the monitor is already active, the pacemaker is automatically interrogated and the trend histogram(s) displayed. (If interrogation is unsuccessful, an error message appears. Note the advice given in the error message, and interrogate the trend monitor again by selecting F8 Interrogate Trend).

To enable or reset the monitor:

1. Select the F5 Start Trend (again) function key.

The monitor is activated (or reset). Counting will begin when the programming head is moved at least 15 cm away from the pacemaker.

To inactivate the trend monitor:

1. Select the F7 Turn Off Trend function key.
- The trend monitor is inactivated.

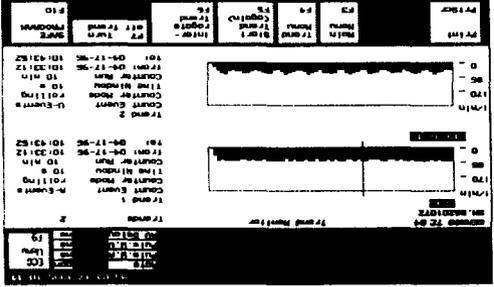


Figure 13. Trend Monitor

6.5 Trend Data

Upon pacemaker interrogation, the recorded trends are displayed as histograms. A cursor line is located in one of the time windows of a trend. The corresponding time point is displayed below the cursor line. The average number of the trend events recorded per minute is displayed above the cursor line. If the cursor line is moved along the trend, the exact data for each individual time window is displayed.

To view time window data:

1. In the **Trend Monitor** window:
 - Select the desired time window
 - Press **Tab** to toggle between the trend parameters and the histogram cursor line. Use the up/down arrow keys to move the cursor from one trend to another and the left/right arrow keys to move the cursor line along the trend display.

To manipulate the trend monitor data:

1. Select **F4 Trend Menu**.
2. Select the desired operation (e.g., **Trend 1 - Trend 2**). The results are displayed in an inset window.

NOTE: The trend monitor inactivates automatically when the replacement indication has been reached.

6.7 Patient Data

[Dromos DR, SR; Gamnos TC 04]

6.7.1 Introduction

Patient data can be stored in the **Patient Data** memory. The stored data is interrogated at the same time as the pacemaker program. If no patient data has been entered, the values are displayed as "xxxx".

The following patient data can be stored:

Patent identification (four characters, letters or numbers)	Symptom	The code for the symptom
Aetiology	The code for aetiology	
ECG indicat.	The code for ECG*	
Last Follow-up	The date of the last follow-up examination	
Lead(AV)	The polarity of the implanted leads (in both chambers)	
Implantation	The date of implantation	

*See listing in European Pacemaker Identification Card (Figure 15)

The contents of **Patient Data** are automatically printed simultaneously with the pacemaker program in all pacemakers with a patient data memory.

NOTE:

Information can be edited but not deleted once information has been entered into the Patient Data Memory.

6.7.2 Procedure

To view the patient data:

1. Open the **Main Menu** and select **Patient Data**.

The patient data display appears.

To enter or edit the patient data:

1. To enter the patient's name, open the value window for **Patient** and enter a four character representation of the patient's name. Select the **↵** key or **Enter** to confirm.
2. To enter the codes for **Symptom**, **Aetiology** and **ECG Index**, open the appropriate value window and select the relevant code.
3. To enter the polarity of the implanted leads, open the value window for **Lead (A/V)** and select the lead polarity(ies).
4. To enter the date of implantation, open the value window for **Implantation**. Enter the date and then select the **↵** key or **Enter** to confirm.

To store the entered/edited patient data:

1. Select the **F5 Transmit Patient Data** function key.

The displayed data is transmitted to the pacemaker's memory and will appear next time the patient data window is opened.

NOTE:
The date of the last follow-up examination is entered automatically when the pacemaker is programmed or if any items within the patient data memory are altered.

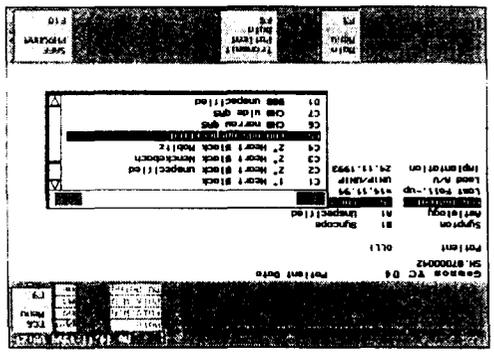


Figure 14. Patient Data

7. Printing

The printer in the programmer is used for documenting the ECG tracings, output pulse measurements and program data. The printer can be used either as an ECG recorder or as a program printer.

NOTE:

Thermal printer paper will fade over time

7.1 Printing ECGs

All functions associated with displaying and printing ECG tracings are controlled using the ECG menu. Descriptions of the various procedures can be found in the ECG section of the *PMS 1000 Programming and Monitoring System Technical Manual*.

7.2 Print Destination

The data can either be printed directly on the printer of the programmer and/or be sent to the patient data system SPS via the serial connection RS 232 (Interface 2).

- To select print destination:
1. Open the **Print Destination** window in the **System Functions**.
 2. Select the desired value.
- All printed data will be sent to the selected print destination

7.3 Printing Measured Values

7.3.1 Printing ECG data

- To print ECG data:
1. Open the **ECG Menu**.
 2. Select the **2 Print Measure** function key.
- The displayed measured values are printed and/or transferred to the patient data system.

7.3.2 Printing Program Data

Displayed program data can be printed from any window to the selected print destination when the **Print Print** key appears on the screen

- To print displayed program data:
1. Select the **Print Print** function key.
- The program data displayed on the screen is printed immediately and/or transmitted to the patient data system SPS.

NOTE:

To avoid paper jams, do not block the printer paper path.



CODE EXPLANATION FOR IMPLANTATION

<p>① FUNCTION</p> <p>FUNCTIONS: 1. 1. Normal 2. 2. Standby 3. 3. Asynchronous 4. 4. Demand 5. 5. VVI 6. 6. DDD 7. 7. DDDR 8. 8. VDD 9. 9. VDDDR 10. 10. VDDDR</p>		<p>② MODE</p> <p>MODES: 1. 1. Normal 2. 2. Standby 3. 3. Asynchronous 4. 4. Demand 5. 5. VVI 6. 6. DDD 7. 7. DDDR 8. 8. VDD 9. 9. VDDDR 10. 10. VDDDR</p>	
<p>③ ANTICLOCK</p> <p>ANTICLOCK: 1. 1. Normal 2. 2. Standby 3. 3. Asynchronous 4. 4. Demand 5. 5. VVI 6. 6. DDD 7. 7. DDDR 8. 8. VDD 9. 9. VDDDR 10. 10. VDDDR</p>		<p>④ MODE</p> <p>MODES: 1. 1. Normal 2. 2. Standby 3. 3. Asynchronous 4. 4. Demand 5. 5. VVI 6. 6. DDD 7. 7. DDDR 8. 8. VDD 9. 9. VDDDR 10. 10. VDDDR</p>	

Figure 15. Code List from the European Pacemaker Identification Card

Notes:

Notes:



PMS 1000

Programming and Monitoring System

TECHNICAL MANUAL

 **BIOTRONIK**

CAUTION: Federal (U.S.A.) law restricts this device to sale by, or on the order of, a physician

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IV PMS 1000 Technical Manual

Preface

This technical manual describes the procedures necessary for operating the PMS 1000 programming and monitoring system. The technical specifications of the PMS 1000 programming and monitoring system are provided herein and descriptions of how the system may be used in conjunction with specified BIOTRONIK pulse generators.

Please refer to the appropriate software manual for device specific operation.

NOTE: The programmability of pacing modes, parameters, and parameter values is determined by the software version installed in the PMS 1000.

Detailed descriptions of pacemaker specific functions are contained in the corresponding pacemaker technical manual.

General Description

PMS 1000 Programming and Monitoring System

The programming and monitoring system (PMS 1000) is a portable device which is powered by AC current. This system is intended to be used to program and monitor implantable pulse generators during implantation and subsequent follow-up examinations. The PMS 1000 provides the following functions within a single system: programming, monitoring, ECG features, and printer.

The PMS 1000 contains the following components:

- EPR 1000 External programming device with internal software module SWM 1000/..
- PGH 1000 Programming head
- EPR 1000 Pen Set Touch-pen and pen holder (for EPR1000)
- NK-3 Power cable
- PK-4 Patient/ECG cable
- PK-4 Adapter Patient/ECG lead adapter for adhesive electrodes
- PMS 1000 screwdriver
- EPR 1000-P Folded thermal paper
- PMS 1000 Manual Programmer technical manual
- SWM 1000 Manual Software technical manual
- PMS 1000 Soft Case Carrying case

All components of the PMS 1000 should be stored in the supplied carrying case.

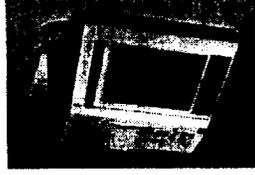


Figure 1. EPR 1000 Programming Device

EPR 1000 External Programming Device

The programmer consists of the following modules:

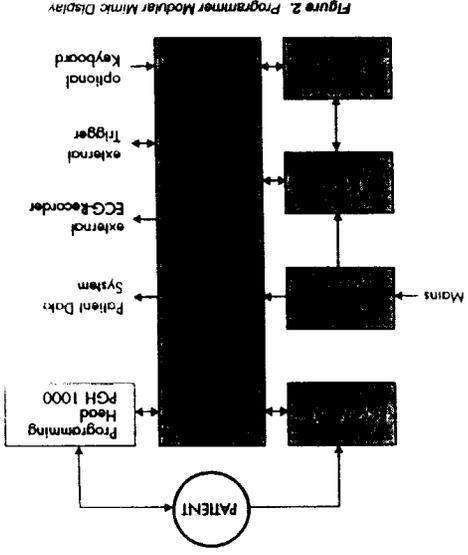


Figure 2. Programmer Modular Mimic Display

Power Supply Unit

The programmer is supplied with power exclusively via a mains connection (AC current). The power supply unit is designed for universal operation (i.e. the programmer can be operated using voltages between

329

115 V and 230 V and on line frequencies between 48 Hz and 62 Hz without the need for an additional range switch).

Computer and Screen

The programmer basic unit operates in a DOS based environment. The programmer has a large, illuminated, LCD screen with a resolution of 640 x 480 image points (VGA). The screen has a high-resolution matrix for controlling the computer interactively from the screen using a touch-pen. In addition to the Program and ECG Display, the screen also contains all the active elements (function keys) used to control the Programmer's functions.

The system is operated by touching the surface of the screen with the touch-pen. The pen works in the following way: resonance is created through capacitive coupling between the pen and the corresponding point of the screen matrix when the pen touches the surface of the screen. In order to trigger a new resonance point, the pen must first be lifted and a new point touched. This prevents a new screen element from being activated by an unintentional movement of the pen on the surface of the screen.

The pen requires no electrical connection to enable it to control the programmer via the screen. The elastic line which connects the pen to the programmer is present only to prevent it from being misplaced. Additionally, all of the programmer's functions can be activated and deactivated using an external PC keyboard connected to the programmer.

In addition to the on-screen keys, the programmer and the programming head have integrated hardware keys which can be used to activate selected functions for safety reasons.

The screen can be tilted up to a 15° angle in eight different self-locking positions to allow for optimal viewing.

ECG Module

The ECG module enables the programmer to be utilized as a three-channel ECG recorder. The PK-4, patient/ECG cable transmits the surface ECG to the programmer via three channels. The programmer continuously displays the registered information from one of these three channels on the LCD screen.

The automatic function for measuring and monitoring the implanted pacemaker is active simultaneous with the surface ECG. ECG signals received from the PK-4 patient/ECG cable are analyzed and the corresponding values for the rate, atrial pulse width, ventricular pulse width and AV delay are shown to the right of the ECG display. The ECG module operates entirely independent of all pacemaker programming functions (i.e. when the programmer's start-up procedure has been completed successfully, the surface ECG can be selected and observed on the screen and/or printer prior to any communication with an implanted device).

Certain pulse generators provide intracardiac electrograms (IEGM) with analog event markers, in conjunction with the PMS 1000, one channel of event markers, the surface ECG, and two IEGM channels can be displayed on the screen to facilitate the identification of ECG complexes. For the generators which provide these features, refer to the appropriate technical manual.

The printer allows the user to print four active ECG channels in real time. Three surface ECG channels, or, depending on whether or not the corresponding function is available and activated, an event marker channel, one surface ECG channel, and two IEGM channels can be simultaneously printed. The printed signals are scaled using calibration pulses which are emitted at the start of each printout.

Printer

The programmer contains a fast, high-resolution, thermal printer. The printer is used to print all program data as well as recording information received from the four ECG channels.

The printer uses fanfold thermal paper. When the paper tray lid is open, the printer is switched off allowing paper to be safely loaded. When the paper tray lid is closed, the printer is switched on automatically. The paper is automatically advanced to the next perforated edge using the printed markings. This procedure eliminates the need for a 'Form feed' key.

Control Module and Interface

The control module connects the various components and the external connections to the interfaces of the programmer.

The programmer has the following interfaces for external communication:

- Programming Head** For connecting the PGH 1000 programming head
- Keyboard** For connecting an external keyboard (IBM, PC, compatible), e.g. to facilitate entry of patient data
- Interface 1** Parallel interface
- Interface 2** Serial interface RS232, e.g. to connect a patient data system (cable EK-10, EK-11, EK adapter)
- ECG Input** For connecting a patient/ECG cable for the surface ECG leads (PK-4)
- ECG Output** For connecting with an external ECG printer or monitor for simultaneous recording of IECG(s) with markers and the surface ECG (e.g. using the PK-24 cable)

PGH 1000 Programming Head

Communication between the programmer and the implanted device (e.g. a pacemaker) takes place by means of a PGH 1000. Data is transferred through induction coils in the programming head and the pacemaker. Both digital and analog data may be transferred by means of digitally-coded pulses. In addition to the coils used for inductive data transfer, the programming head contains a permanent magnet. A reed switch within the pacemaker is closed by holding the programming head (magnet) a maximum of 50 mm from the pacemaker. Communication cannot take place when the reed switch is open, which offers additional protection against accidental reprogramming. In pacemakers, the closing

of the reed switch may also cause the device to convert to an asynchronous pacing mode (for specific pacemaker behavior, please refer to the appropriate technical manual).

To facilitate positioning, the programming head is fitted with an indicator light which blinks when telemetry is established.

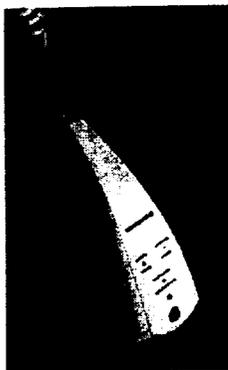


Figure 3. PGH 1000 Programming Head

Cautions

Programmer Repair

The PMS 1000 may only be opened or repaired by the manufacturer or by personnel authorized to do so by the manufacturer.

Faulty Fuses

Faulty fuses indicate a possible fault in the device. Inspection B must therefore be carried out after the fuses have been replaced (see Maintenance and Service, page 55)

Basic Functions

Preparing the Programmer

Remove the programmer and the other components of the PMS 1000 from the carrying case. Peel off the protective film from the LCD screen. Expose the adhesive strip on the back of the pen holder and attach it to the frame of the programmer screen. The pen holder can be attached to any desired position on the screen frame, depending on the position from which the device is to be operated. Care should be taken to avoid placing the pen holder over the Safe Program key on the front left side of the screen frame.

Connect the PGH 1000 programming head to the corresponding port designated on the rear of the right-hand side of the programmer. Use the enclosed screwdriver to screw the connection tight.

Mounting the Programming Head Holder

The programming head holder offers a safe place to store the PGH 1000 during transport and operation. The holder can be positioned to a convenient angle for the user. Mount the holder on the right side of the programmer. The programming head stays connected while the holder is assembled.

Place the programmer on its left side. Adjacent to the PGH 1000 connection are four holes. The holes near the upper side are for the digi-L-shaped hooks of the holder. The holes at the lower side are for the four small hooks of the holder. Next, position the holder such that the four hooks point to their corresponding holes. Insert the hooks into their holes by moving the complete holder toward the face of the programmer. All four hooks must sit in their holes. Move the holder toward the rear side of the programmer until it stops.

Secure the holder by sliding the white plastic lock toward the face of the programmer. The holder is properly mounted only if the white fls fits into its hole.

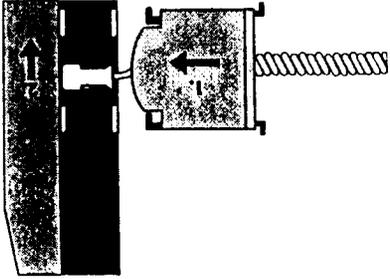


Figure 4. Programming Head Holder

Inserting Paper into the Printer

Open the paper tray lid.

NOTE: Lid does not open fully, do not extend the lid beyond its catch.

Cut off the delineated triangular (upper right) piece of paper from the top sheet of the stack. Should a partially-used stack of printer-paper be loaded, the triangular delineation is diagramed on the paper stack filler in the bottom of the paper tray.

Put the paper stack into the printer tray so that the tip of the top sheet is pointing towards the printer slot. Push the top sheet into the printer slot and pull it through until the full width of the sheet appears beyond the printer. Close the paper tray lid. The paper will advance to the start of the next page.

NOTE: To avoid paper jam do not block the printer slot!



Figure 5. Inserting Printer Paper

Removing Printer Paper

Open the paper tray lid. Pull the paper completely out of the printer slot. Use the filter to remove the paper stack from the paper tray.

Switching on the Programmer

Connect the NK-3 power cord to the corresponding port designated on the left-hand side of the rear of the programmer. The power switch is located directly next to the power cord connection (on the left side of the rear of the programmer).

Switch on the programmer. Once switched on, the device conducts a self-test. When this has been completed successfully, a list of the pacemakers which can be programmed with the software module appears on the screen.

Tilting the Screen

The screen can be tilted up to a 15° angle in eight different self-locking positions to allow for optimal viewing. Gently lift up or press down on the top of the screen frame so that reflections glare on the screen are minimized.

Setting the Contrast

Use the dial, located in the depression on the right-hand side at the front of the programmer, to set the contrast and the brightness of the screen display.

Replacing the Pen

A spare pen is mounted on the underside of the programmer. Remove the cap and the elastic line from the old pen. Gently lift the front of the programmer. Remove the spare pen from the holder. Place the cap and the elastic line onto the spare pen.

Transporting the Programmer

Switch off the programmer and disconnect all cables. Gently lift the front of the programmer, and swing the handle on the underside of the front of the device forward. Carry the device using its handle.

Transporting/Storing the Complete PMS 1000 System

The complete PMS 1000 system is best transported/stored in its carrying case. Switch off the programmer and disconnect all cables. Place all components into their designated storage compartments. If the hard case is used, disconnect the programing head holder first. Unlock the holder by sliding the white lock away from the face of the programmer. Move the holder to the front side of the programmer until it stops. Move the holder to the lower side of the programmer to release the hooks

Basics of Screen Operation

All functions can be operated with the pen or with an external PC keyboard, with the exception of switching the power on and off (U0) and adjusting the screen contrast. Screen elements can be tapped with the pen or selected with the corresponding keys of the keyboard.

Screen Layout

The screen is divided into four areas. At the top there is an area for displaying event markers (on the left) and the time and date (on the right). The area below is used to display and operate the surface ECG and the associated monitoring function. The largest area in the center of the screen is used in a number of ways to display and control all the parameters and program functions. The lower area contains the main operating keys for the current screen.

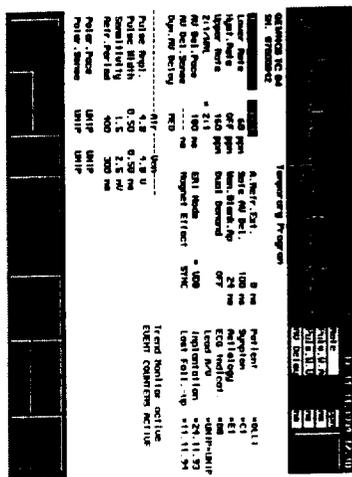


Figure 6: Screen Layout

Description of the Screen Elements

Parameters

Parameters are elements of a program which define the operation of a pacemaker. Parameters consist of names, values and units of measurement (optional). Touching a parameter on the screen opens a window with the parameter's potential values.

A broken line is shown instead of the value for parameters with no application to the selected pacemaker mode. If these parameters become adjustable, due to a change in mode, their standard values are displayed.

Passive Parameters

Passive parameters have either a fixed value or a value which is automatically set by the software. Passive parameters cannot be selected and are therefore marked with an asterisk (*).

Parameter Conflicts

Certain parameter values or combinations of values of different parameters may, for technical or safety reasons, be blocked from programming. These blocked values are marked > or >> indicating a parameter conflict both in the parameter display and in the value window.

Parameter conflicts marked >, although blocked from the permanent program, can be programmed temporarily. Parameter conflicts marked >> cannot be programmed.

Keys

Keys are only displayed when they have a function. Keys may either trigger a function directly or open a window containing a menu. Each key contains the descriptive name of a function as well as the allocated key on a PC keyboard.

F5

This key appears on certain displays and menus as an additional function key with a specific function

F6 Interrogate

Touching this key sends a command to identify the pacemaker. After successful identification, the pacemaker is interrogated. In the function displays, the key, with a suitable designation, is used for particular types of interrogations (e.g., Interrogate Trend).

F7 Transmit Temporary

This key only appears with this designation on program displays in which the pacemaker can be programmed temporarily. In the function displays the key, with suitable designations, is used to start or abort functions which act as temporary programs (e.g., Start Test).

F8 Transmit

This key only appears in the Program Display. Touching the key transmits the displayed program as a permanent program

F9 ECG Menu

This key appears when an interface is available with which ECG signals can be evaluated.

Touching the key opens a window with a menu of all the functions used to control the display and printing of ECGs and IEGMs.

F9 Stop ECG Print

This key only appears if the window with the ECG menu is closed while an ECG is being printed. Touching the key aborts ECG printing

F10 Safe Program

This key is always present. Touching the key transmits the safe program as a permanent program.

Additional keys may appear on the screen, as well as the main function keys described above.

Windows

Windows may contain text, menu entries, parameters, values and keys. Windows are opened automatically when additional information is selected. When several windows are open, the window which was last opened is the active window.

Activating On-Screen Elements

Elements on the screen (parameters, values, menu entries and function keys) are activated by touching them on the screen using the pen or using a PC keyboard which is externally connected to the programmer. In the following description, the two methods of activating on-screen elements are denoted as follows:

- Activation using the pen.
- Activation using a PC keyboard.
- Selecting parameters or menu entries**
 -  Use the pen to touch the parameter or the menu entry.
 - Use the arrow keys to position the cursor on the required parameter or menu entry.
- Activating key functions**
 -  Use the pen to touch the required key.
 - Press the denoted key on the keyboard.
- Closing the current window**
 -  Use the pen to touch the Esc key in the current window or touch an empty space in the higher level window
 - Press the Esc key on the PC keyboard.

Closing all windows

- ☛ Use the pen to touch an empty space on the screen outside the opened windows.
- ☛ Repeatedly press the **Esc** key on the PC keyboard until all windows are closed.

Closing windows and activating new functions

- ☛ Use the pen to touch a screen element outside the current window.
- ☛ Press the required function key on the PC keyboard or repeatedly press the **Esc** key on the PC keyboard until all windows are closed and then select a new screen element.
- ☛ The window is closed automatically and the function of the selected screen element is activated.

Closing value windows and activating values

- ☛ Use the pen to touch the required value or first touch one of the arrows on the scroll bar to scroll the value range. Touch the required value on the screen or touch the **Ok** key in the window.
- ☛ After the value has been touched in the window, the window is closed and the value which has been selected with the cursor is incorporated in the Parameter Display.
- ☛ Use the arrow keys on the PC keyboard to position the cursor on the required value and confirm the selection by pressing the **Enter** key on the PC keyboard.

Closing the value window without activating a value

- ☛ Use the pen to touch the **Esc** key in the window or touch an empty space on the screen outside the open window. If a different parameter is touched outside the current window, the previous value window is closed and a new value window is opened immediately.
- ☛ Press the **Esc** key on the PC keyboard.

Screen Hierarchy

- Overview Menu - Lists of implants
- Program Display - Basic pacemaker program
- Function Displays - Specific additional functions of the pacemaker

System Functions

The system functions window contains basic settings which optimize the hardware configuration of the PMS 1000 as well as specific settings for customized operation of the PMS 1000 according to personal requirements. All settings are stored automatically and are available for use after the device is switched off and on again.

- Use the pen to touch the **F3 Main Menu** key. Next touch System Functions in the menu window.
- Press the **F3** function key on the PC keyboard. Next use the arrow keys to position the cursor on **System Functions** and keyboard confirm the selection by pressing the **Enter** key on the PC

A system functions window is opened.

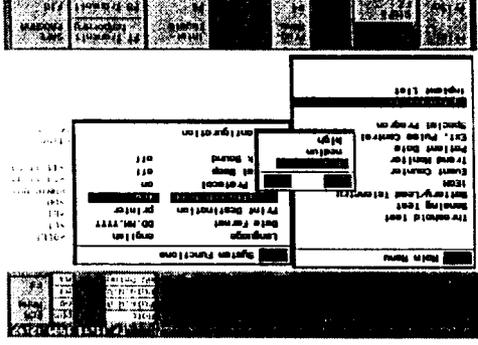


Figure 11. System Functions

Language

All on-screen displays may be set to appear in different languages. This setting relates both to what is displayed on the screen and to printouts.

- Use the pen to touch the **Language** parameter in the System Functions menu. Touch the required value in the value window.
- Use the arrow keys to position the cursor on **Language** in the System Functions menu and confirm the selection by pressing the **Enter** key on the PC keyboard.

The date format may be set to Day, Month, Year (DD.MM.YYYY) or Month, Day, Year (MM.DD.YYYY). This setting relates both to what is displayed on the screen and to printouts.

Date Format

- Use the pen to touch the **Date Format** parameter in the System Functions menu. Touch the desired format in the value window.
- Use the arrow keys to position the cursor on **Date Format** in the System Functions menu and confirm the selection by pressing the **Enter** key on the PC keyboard.

position the cursor on the desired date format in the value window and confirm the selection by pressing the **Enter** key on the PC keyboard.

Print Destination

Touching the **Print** key, printer data may be transmitted either directly to the internal printer PRT 1000 and/or via the serial interface RS 232 (interface 2) to the patient data system SPS.

- Use the pen to touch the **Print Destination** parameter in the System Functions menu. Touch the desired format in the value window.
- ☐ Use the arrow keys to position the cursor on **Print Destination** in the System Functions menu and confirm the selection by pressing the **Enter** key on the PC keyboard. Use the arrow keys to position the cursor on the desired date format in the value window and confirm the selection by pressing the **Enter** key on the PC keyboard.

Sensitivity of the Programming Head

The sensitivity of the PGH 1000 programming head has three settings

LOW: For reducing electromagnetic interference

- Use the pen to touch **Sensitivity PGH 1000** in the System Functions menu. Touch **Low** in the value window.
- ☐ Use the arrow keys to position the cursor on **Sensitivity PGH 1000** in the System Functions menu and confirm the selection by pressing the **Enter** key on the PC keyboard. Use the arrow keys to position the cursor on **Low** in the value window and confirm the selection by pressing the **Enter** key on the PC keyboard.

NOTE: Reducing the sensitivity of the programming head reduces its range.

MEDIUM:

- For normal operation
- Use the pen to touch the **Sensitivity PGH 1000** parameter in the System Functions menu. Touch **Medium** in the value window.
- ☐ Use the arrow keys to position the cursor on **Sensitivity PGH 1000** in the System Functions menu and confirm

the selection by pressing the **Enter** key on the PC keyboard. Use the arrow keys to position the cursor on **Medium** and confirm the selection by pressing the **Enter** key on the PC keyboard.

HIGH: For greater range requirements.

- Use the pen to touch **Sensitivity PGH 1000** in System Functions menu. Touch **High** in the value window.
- ☐ Use the arrow keys to position the cursor on **Sensitivity PGH 1000** in the System Functions menu and confirm the selection by pressing the **Enter** key on the PC keyboard. Use the arrow keys to position the cursor on **High** in the value window and confirm the selection by pressing the **Enter** key on the PC keyboard.

NOTE: A high sensitivity of the programming head increases the chance of receiving electromagnetic interference. Switching off all sources of noise may be necessary.

Switching the Test Protocol On/Off

The test protocol provides an automatic ECG printout which occurs during the threshold and sensing tests.

- Use the pen to touch **Test Protocol** in the System Functions menu. Next touch either **On** or **Off** in the value window.
- ☐ Use the arrow keys to position the cursor on **Test Protocol** in the System Functions menu and confirm the selection by pressing the **Enter** key on the PC keyboard. Next use the arrow keys to position the cursor on either **On** or **Off** in the value window and confirm the selection by pressing the **Enter** key on the PC keyboard.

Acoustic Signal

This setting is used to set an additional acoustic signal to indicate whether interrogation or transmission was successful. The acoustic signal emitted varies according to its function:

- 3 high-pitched beeps:** Indicates "Unsuccessful" (e.g. if the program was not transmitted due to interference)
- 1 low-pitched beep:** Indicates "Successful" (e.g. if the program was transmitted successfully)

- ☞ Use the pen to touch **Signal Beep** in the System Functions menu. Next touch either **On** or **Off** in the value window.
- ☑ Use the arrow keys to position the cursor on **Signal Beep** in the System Functions menu and confirm the selection by pressing the Enter key on the PC keyboard. Next use the arrow keys to position the cursor on either **On** or **Off** in the value window and confirm the selection by pressing the Enter key on the PC keyboard.

Click Sound

A quiet click sound may be switched on or off to confirm that the pen has touched an element on the screen.

- ☞ Use the pen to touch **Click Sound** in the System Functions menu. Next touch either **On** or **Off** in the value window.
- ☑ Use the arrow keys to position the cursor on **Click Sound** in the System Functions menu and confirm the selection by pressing the Enter key on the PC keyboard. Next use the arrow keys to position the cursor on either **On** or **Off** and confirm the selection by pressing the Enter key on the PC keyboard.

PC Configuration

The PC Configuration allows the set up of some PC hardware functions. These settings are saved automatically and are available even after switching the PMS 1000 off and on again.

- ☞ Use the pen to touch **PC Configuration** in the System Functions menu.
 - ☑ Use the arrow keys to position the cursor on **PC Configuration** in the System Functions menu and confirm the selection with the Enter key on the PC keyboard.
- A window with PC Configuration settings is opened.

Setting the Date

The date in the built-in clock may be set. The clock continues to function when the PMS 1000 is switched off. In addition, the calendar takes leap years into account. The date is displayed on the screen and on printouts.

- ☞ Use the pen to touch the **Date** parameter in the System Functions menu.
 - ☑ Use the arrow keys to position the cursor on **Date** and confirm the selection by pressing the Enter key on the PC keyboard.
- A keyboard and an entry field appear on the screen.

☞ Touch the desired numeral on the on-screen keyboard or change the value at the cursor position using the + and - keys on the on-screen keyboard. The cursor position is indicated by a small line below the relevant numeral. The cursor can be moved using the arrow keys.

☑ Press the desired numeral on the PC keyboard or change the value at the cursor position using the + and - keys on the PC keyboard. The cursor position is indicated by a small line below the relevant numeral. The cursor can be moved using the arrow keys.

The previous date settings are replaced by the new settings.

New Date

If the entered date is to be incorporated:

- ☛ Touch the **Enter** key on the on-screen keyboard to confirm the setting.
- ☑ Press the **Enter** key on the PC keyboard to confirm the setting.

Unchanged Date

If the previous setting is to remain unchanged, close the window without confirming the new setting.

Setting the Time

You may set the time of the built-in clock which appears on the screen and on printouts.

- ☛ Use the pen to touch **Time Setting** in the System Functions menu.
- ☑ Use the arrow keys to position the cursor on **Time Setting** in the System Functions menu and confirm the selection by pressing the **Enter** key on the PC keyboard.

A keyboard and an input field appear on the screen.

- ☛ Touch the desired numeral on the on-screen keyboard or change the value at the cursor position by touching the + and - keys on the on-screen keyboard. The cursor position is indicated by a short line below the relevant numeral. The cursor may be moved using the arrow keys.
- ☑ Press the desired numeral on the PC keyboard or change the value at the cursor position by pressing the + and - keys on the PC keyboard. The cursor position is indicated by a short line below the relevant numeral. The cursor may be moved using the arrow keys.

The previous time setting is replaced by the new settings.

Adjust Time

If the new time setting is to be incorporated:

- ☛ Touch the **Enter** key on the on-screen keyboard to confirm the setting.
- ☑ Press the **Enter** key on the PC keyboard to confirm the setting.

Unchanged Time

If the original time setting is to remain unchanged, close the window without confirming the setting.

PC Keyboard

You may select the type of keyboard that shall be connected to the programmer.

- ☛ Use the pen to touch the **PC Keyboard** parameter in the System Functions menu. Touch the desired format in the value window.
- ☑ Use the arrow keys to position the cursor on **PC Keyboard** in the System Functions menu and confirm the selection by pressing the **Enter** key on the PC keyboard.

Mains Frequency

By specifying the line frequency of the AC current supply, the ECG filter, which can be activated in the ECG menu, can function more precisely. If the line frequency is accidentally specified incorrectly, interference in the ECG signal may not be filtered out optimally. Other functions are not affected adversely. It is not necessary to select power supply voltage, since the mains connection automatically sets itself to the correct setting.

- ☛ Use the pen to touch **Mains Frequency** in the System Functions menu. Next touch either **50 Hz** or **60 Hz** in the value window.
- ☑ Use the arrow keys to position the cursor on **Mains Frequency** in the System Functions menu and confirm the selection by pressing the **Enter** key on the PC keyboard. Next use the arrow keys to position the cursor on **50 Hz** or **60 Hz** in the value window.

and confirm the selection by pressing the Enter key on the PC keyboard.

NOTE: For U.S. applications the 60 Hz setting should be selected.

ECG Functions

ECG functions are independent of the functions used by the programmer to program pacemakers.

ECG Menu

- Use the pen to touch the F9 ECG Menu key.
- Press the F9 function key on the PC keyboard

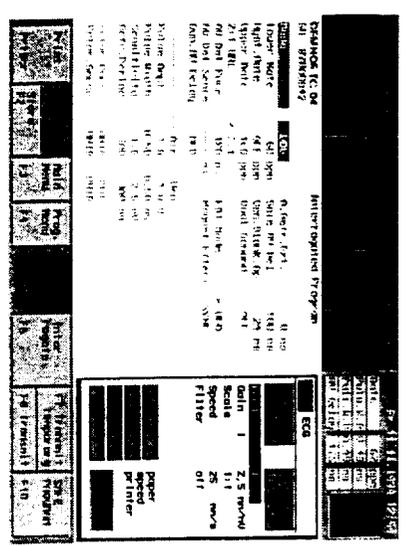


Figure 12. ECG Menu

Switching the ECG On/Off

The on-screen representation of the ECG can be switched on and off.

- Use the pen to touch the 1 ECG On key or the 1 ECG Off key.
- Press the numerical key 1 on the PC keyboard.

The ECG can be printed independently of the on-screen representation.

Selecting Leads

This parameter is used to select the leads for the surface ECG which is displayed on the screen or printed together with the IEGM.

Open the value window for Lead and select the desired value

Setting Gain

This parameter is used to set the amplification of the three surface ECG leads both for the on-screen representation and for printouts.

Open the value window for Gain and change the value until the optimum ECG is displayed.

Setting the Scale

The surface ECG screen display can be enlarged. This enlargement is linear and may be up to a value of 4:1 without affecting the signal amplification or the signal-noise ratio. Scaling does not affect the amplitude on the printout.

Open the value window for Scale and change the values until the optimum ECG size is displayed.

Setting the Scroll Speed

These parameters are used to set the speed of the on-screen representation of the surface ECG and the IEGM.

Open the value window for Speed and change the values until the ECG display scrolls across the screen at the desired speed. The paper speed of the printout is not affected by this setting.

Switching the Filter On/Off

This parameter is used to switch the filter, which suppresses line frequency interference on the surface ECG, On and Off. The filter influences the on-screen representation and printouts.

Open the value window for Filter and select either On or Off.

Printing the ECG

If only the surface ECG is displayed on the screen, all three channels are automatically printed out when printing occurs. When the IEGM is transmitted, the channel of the surface ECG currently displayed on screen is printed simultaneously with the IEGM and the analog event markers (Pace, Sense, Unused Sense).

- Touch one of the keys on the screen used to set the paper speed (e.g., 50 mm/s).
- ▢ Press one of the keys on the PC keyboard used to set the paper speed (e.g., the numerical key 3, which sets the paper speed at 50 mm/s).

In addition to channel identifier and annotations, the printout is furnished with a calibration pulse in each channel. In contrast to the surface ECG in which the calibration pulse is always standardized to 1.0 mV, the level of the calibration pulse for IEGMs is always equivalent to the maximum modulation range. In unfiltered IEGMs, this value is always 20 mV. In filtered IEGMs, the amplitude of the calibration pulse is twice the value of the programmed sensitivity of the pacemaker.

Stopping the ECG Printout

If the window with the ECG menu is open:

- Touch the 7 Off key in the ECG menu.
- ▢ Press the numerical key 7 on the PC keyboard.

Printing is stopped.

If the window with the ECG menu is not open:

- Touch the F9 Stop ECG Print key.
- ▢ Press the F9 function key on the PC keyboard.

Printing is stopped and the ECG window is opened.

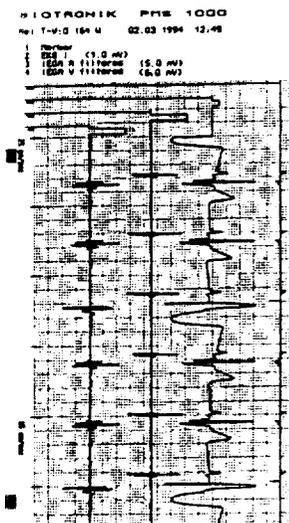


Figure 13. Printout of Markers, ECG, Atrial and Ventricular IEGM

Connect the ECG output of the programmer to the ECG recorder's DC input using the appropriate interface cable.

General Program Functions

Pacemaker List

A list of the pacemakers programmable with this software appears after completion of the self-test. Refer to the appropriate software manual for specific details.

Displaying the Pacemaker List

- Use the pen to touch the **F3 Main Menu** key. Next touch **Implant List** in the menu window.
- ☑ Press the **F3** function key on the PC keyboard. Next use the arrow keys to position the cursor on **Implant List** and confirm the selection by pressing the **Enter** key on the PC keyboard.

NOTE: If a pacemaker has already been interrogated, selecting **Implant List** will erase all previously interrogated data of this pacemaker within the programming device.

1. If the stored data is no longer required:
 - Touch the **OK** key on the screen.
 - ☑ Press the **Enter** key on the PC keyboard.
2. If the stored data is still required, close the window without confirming.

Selecting a Pacemaker from the List

- Use the pen to touch the desired pacemaker.
 - ☑ Use the arrow keys to position the cursor on the desired pacemaker and confirm the selection by pressing the **Enter** key on the PC keyboard.
- The standard program of the selected pacemaker is displayed on the screen.

Distributed by:
BIOTRONIK
BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035-5369
(800) 547-0394 (24-hour)
(503) 635-9936 (FAX)

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BIOTRONIK GmbH & Co.
W/Seemannkefere 1
D-12359 Berlin
Germany

Patient Manual

What you should know about your pacemaker...

Rev. M3017-E 8/91

*What you should know
about your pacemaker...*

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Introduction...

Your physician has determined that you need a cardiac pacemaker to maintain a continuous and regular heartbeat. Over one million people have benefited and enjoyed a more normal and active life, thanks to a cardiac pacemaker.

The purpose of this publication is to provide you and your family with a better understanding of your cardiac pacemaker. It is not intended to be a substitute for professional diagnosis or advice. You should discuss your specific situation with your physician.

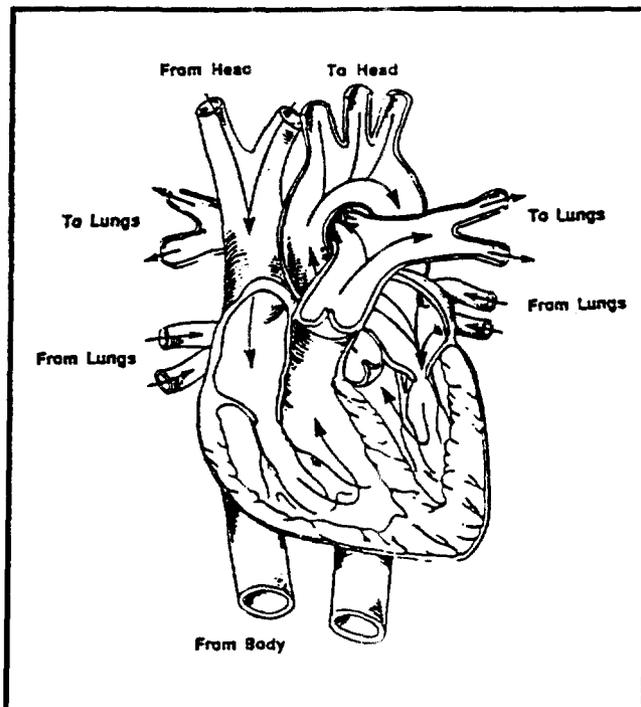
How your natural pacemaker works...

Your heart is a muscular organ weighing less than one pound and is about the shape and size of a clenched fist. It beats at an average rate of 72 beats per minute and pumps blood throughout the body delivering oxygen and nutrients. This is a vital function because without a constant supply of oxygen and nourishment, cells will die.

There are four chambers in the heart: two upper (atria), and two lower (ventricles).

Blood flows out from the heart through the aorta, the largest artery, branching into smaller arteries which carry blood to all parts of the body.

3



After the body's tissues remove oxygen and nutrients, the blood enters the veins and returns to the right atrium where the cycle begins again.

When functioning properly, the heart's rate will increase or decrease with your level of activity.

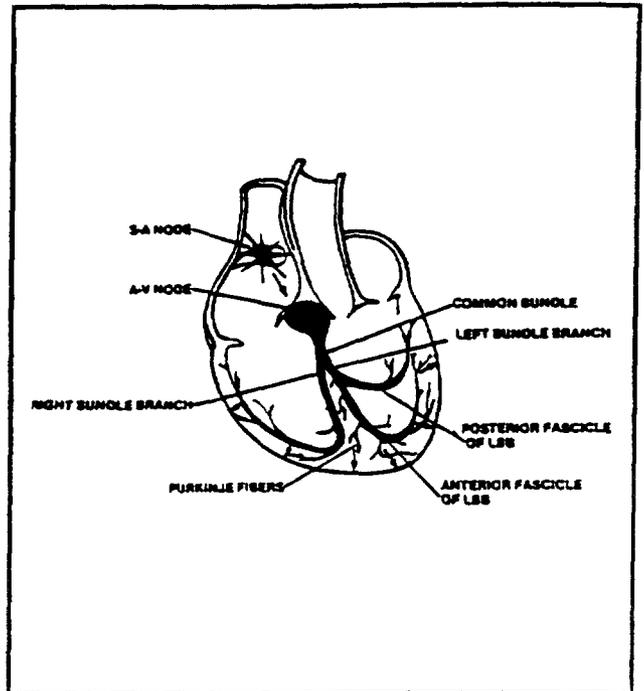
Your heart has its own natural pacemaker which regulates the heart's rate by sending out electrical impulses.

The Blood Circulation System of the Heart.

4

365

Unlike any other muscle in the body, it has a very special feature which generates its own contractions. This is due to a small group of specialized cells located in the upper wall of the right atrium, referred to as the sino-atrial (S-A) node. The S-A node, commonly known as the "natural pacemaker", sends electrical impulses to the heart where beats are generated. These rhythmical beats spread through both atria to the ventricles via another specialized group of conductive cells called the atrio-ventricular (A-V) node. From the A-V node, the impulse continues through the rest of the conductive pathways causing the ventricles to contract.

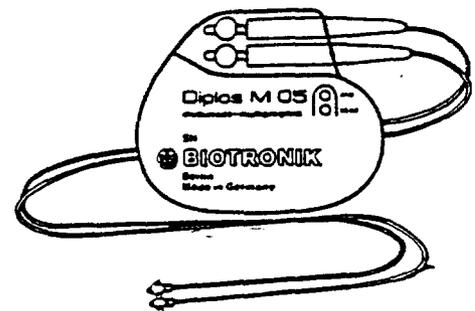


Electrical Circulation System of the Heart

How your implanted pacemaker works...

Sometimes the natural rhythm of the heart becomes impaired. Your natural pacemaker may decrease the number of impulses to the heart resulting in an abnormally slow heart rate, or the heart may stop beating for short periods of time. There may be a "block" in your heart's conduction system preventing electrical impulses from reaching the lower chambers. Whatever the cause, an inadequate supply of oxygen and nutrients to the body can lead to drowsiness, chest pain, shortness of breath, dizziness and, sometimes, loss of consciousness. Your implanted cardiac pacemaker substitutes for your own natural pacemaker. It is a battery-powered system consisting of two components: the pacemaker itself which sends

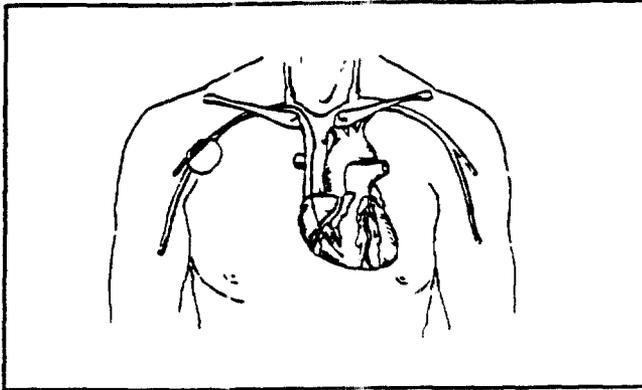
out electrical impulses; and the lead, which is a wire connecting the pacemaker to the heart to stimulate contraction. Different types of pacemakers have been developed to fit individual needs. Today, most pacemakers can be programmed to sense the electrical activity of the heart and function only when your natural pacemaker does not perform properly.



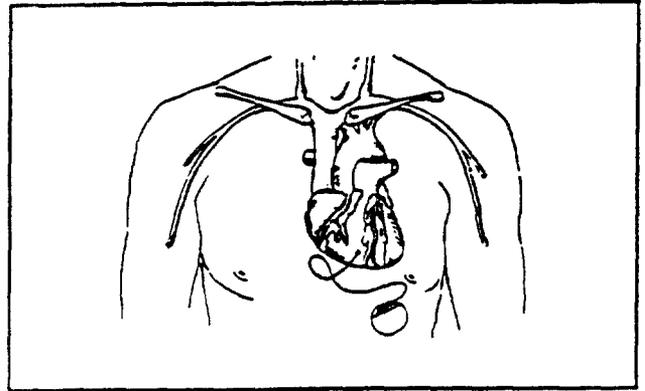
How your pacemaker is implanted...

Your physician will choose one of several methods to surgically implant your cardiac

pacemaker and lead. The method chosen is dependent upon your individual needs.



Placement of the pacemaker in the shoulder region with the lead being introduced into the heart by way of a vein.



Placement of the pacemaker in the abdominal region with the lead being placed directly on the heart muscle.

7

The surgical procedure and afterwards...

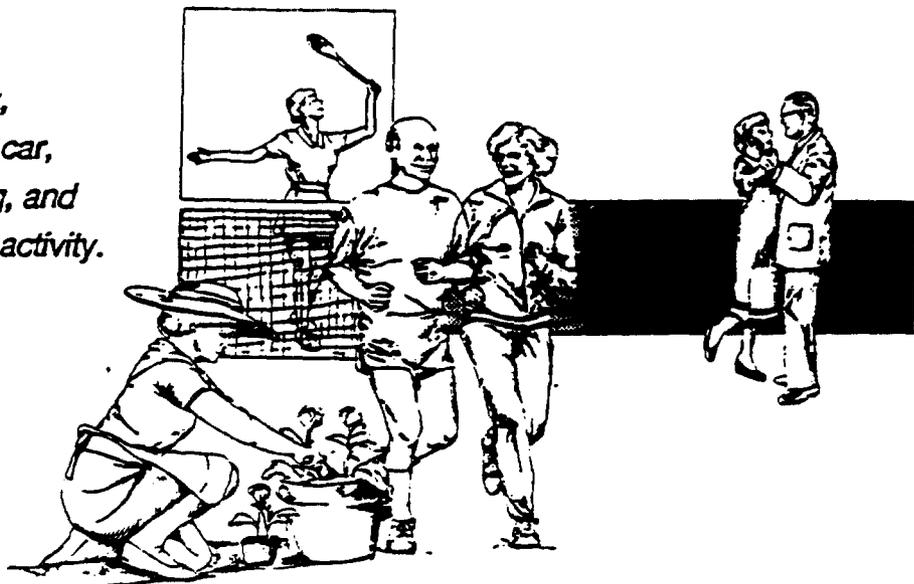
Surgery usually takes only a short time, and your hospital stay will be minimal. The procedure may be performed either under local or general anesthesia, depending on your own particular situation. The physician will make a small incision in the area in which your pacemaker will be implanted. A "pocket" will then be created within the body tissue to allow space for the implanted pacemaker. Then the lead will be introduced either into the vein, or attached directly to the heart. Once the lead is placed, a test will be performed to ensure placement in the correct area of the heart and the lead will then be connected to the pacemaker.

After your pacemaker has been implanted, there may be some temporary soreness and discomfort at the site of the incision. However, you will probably feel better immediately since in most cases your symptoms prior to surgery will have been remedied. At first, the pacemaker may feel heavy, bulky, and sensitive, but this will subside within a short time.

Follow the guidelines your physician has established for you and contact him for advice concerning your levels of activity.

With the advice of your physician, you may return to your normal personal and professional activities, including:

- ♦ *moderately exercising,*
- ♦ *traveling, driving your car,*
- ♦ *swimming and bathing, and*
- ♦ *resuming your sexual activity.*



What to avoid with your pacemaker...

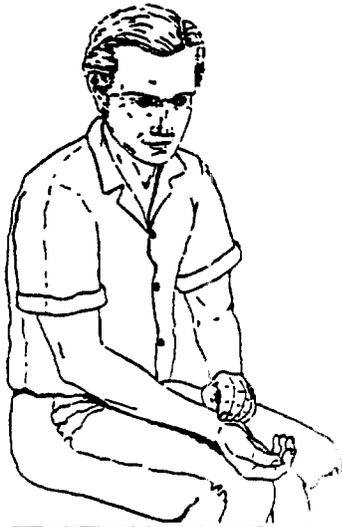
Avoid the urge to move the pacemaker around under the skin, since this may dislodge the lead. Strenuous activities such as contact sports and heavy weightlifting should be avoided. Use caution when reaching over your head or jerking your arm away from your body during the first two months after implant. Do not rest a rifle butt against the pacemaker site since the direct trauma may cause damage to the skin and/or the pacemaker.

If you are being treated with other devices or therapies which may interfere with your pacemaker, always inform your medical professional that you have an implanted pacemaker. Medical treatments such as diathermy, nerve stimulators, electrocautery, and magnetic resonance imaging (MRI) may all adversely affect the pacemaker.

Your pacemaker is enclosed in a protective shield; therefore, outside interference with your pacemaker is most unusual. Strong electromagnetic fields found near military radar installations and power generator plants, as well as radiation from arc welders and induction furnaces, should be avoided at close distances since these may interfere with your pacemaker. Most electrical appliances, including microwave ovens, will not affect your pacemaker unless they are malfunctioning. Vehicle ignition systems, diathermy, shortwave radios, and vibrating chairs or beds may also interfere with your pacemaker's programmed settings. If interference occurs, simply move away from its source.

Checking your pacemaker...

As with any electronic device, your artificial pacemaker will require some care. The average life of a pacemaker depends on how



often it is pacing your heart. The exact lifetime of your pacemaker will depend not only on the model, but on its programmed settings and frequency of pacing. The battery will wear out over time and the pacemaker may need to be re-

placed. However, BIOTRONIK's pacemakers are designed with an early-warning mechanism which will indicate to the physician when the time is approaching for replacement. There will be a gradual decrease in your paced pulse rate, usually by five to ten beats per minute. You need not be alarmed, since this phase usually lasts for several months. It is of utmost importance that you keep your scheduled follow-up appointments.

You may be asked by your physician to monitor your own pulse rate via the telephone between your regularly scheduled office visits.

Monitoring your pacemaker by telephone...

If your physician chooses to monitor your pacemaker by telephone, you will receive a small, portable telephone transmitter that will



enable you to send a recording of your heart's activity to a special recording device. You will receive complete instructions on the use of this device, since each pacemaker company has its own system.

A regular schedule will be established for the nurse to telephone you. You should be

prepared for these telephone appointments.

When you are ready to transmit, turn ON your transmitter, sit quietly, breathe normally and stay relaxed. If you breathe too fast or too deeply during the transmission, your recording may not be accurate. If you are a bit nervous, let your nurse know so that more of the procedure may be explained to you. Actual transmission of your heart's activity will last approximately thirty seconds. When the checkup is complete, an intermittent beeping noise will be the signal to remove the telephone from your transmitter. You may now conduct a normal telephone conversation with the nurse. Turn OFF the transmitter.

When to alert your doctor...

Several physical signs may indicate a complication from your pacemaker implantation. Your doctor should be contacted immediately if any of the following symptoms are apparent:

- ♦ fever along with redness, swelling, or drainage at the surgical site or around the pacemaker,
- ♦ difficulty in breathing, palpitations,
- ♦ dizziness, lightheadedness or fainting spells,
- ♦ prolonged weakness or fatigue,
- ♦ swelling of the legs, ankles, arms, or wrists,
- ♦ chest pains, or prolonged hiccupping.

If your pacemaker needs to be replaced because the battery has worn out over time, only a minor surgical procedure is necessary. Your physician can explain it to you, however, it will not take as long as your first implant surgery.

Your pacemaker identification...

You will receive a temporary identification card upon your release from the hospital. A permanent identification card will be sent to you from BIOTRONIK with all of the information relative to your pacemaker.

PACEMAKER PATIENT IDENTIFICATION CARD			
NAME	John Anybody		
ADDRESS	123 MAIN ST		
CITY	ANYTOWN	STATE	OR
ZIP	98765		
PACER MODEL	SERIAL NO.	IMPLANT DATE	
MANOS BP	12345678	12-31-90	
VENTRICULAR LEAD MODEL	MP-13-8P	123456	
VENTRICULAR LEAD MODEL	V1		
PHONE IN CASE OF EMERGENCY			
IMPLANTING DR:	(123) 555-5555 SMITH		
FOLLOWING DR:	(123) 555-0000 JONES		
BIOTRONIK	24-HR TECH SERVICE		
© BIOTRONIK			

Temporary ID Card

PACEMAKER PATIENT IDENTIFICATION CARD			
JOHN ANYBODY			
123 MAIN STREET			
ANYTOWN, OR 12345			
(503) 987-6543			
PACER MODEL	SERIAL NO.	IMPLANT DATE	
MANOS BP	12345678	12-31-90	
VENTRICULAR:			
ATRIAL:	MP-13-8P	123456	
PHONE IN CASE OF EMERGENCY:			
IMPLANTING DR:	(123) 000-5555 SMITH		
FOLLOWING DR:	(123) 555-0000 JONES		
BIOTRONIK:	(503) 635-3594		
24-HOUR TECH.SERVICE			
© BIOTRONIK			

Permanent ID Card

Your cardiac pacemaker identification card should be carried with you at all times so that medical professionals who may treat you will be aware that you have an implanted cardiac pacemaker.

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Special instructions for the patient...

Physician _____

Telephone Number _____

Pacemaker rate set at _____

Your pulse count should be about _____ beats per minute.

If your pulse rate is less than _____ or more than _____, please call your physician.

Medications	How many	Times per day
-------------	----------	---------------

_____	_____	_____
_____	_____	_____

Physical Activities _____

Restricted Foods _____

Frequency of Follow-up Appointment Schedule _____

15

Manufactured by:

BIOTRONIK GmbH & Co.
Woermannkehre 1
D-1000 Berlin 47
Germany

Distributed by:

BIOTRONIK, Inc.
6024 Southwest Jean Road
Lake Oswego, OR 97035-5369
(800) 547-0394

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