



**This manual describes the operation of a REF 4580 Dual-Chamber
External Cardiac Pacemaker with software version 2.0.**

INSTRUCTION MANUAL

MICRO-PACE™

**REF 4580
DUAL-CHAMBER
TEMPORARY CARDIAC PACEMAKER**

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Waltham, MA 02451
U.S.A

and

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CAUTION: Federal (USA) law restricts
this device to use by or on the order
of a physician.

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Recommended conditions for:

Operation: +10°C (+50°F) to +40°C (+104°F); RH 30% to 70%
 Transport and Storage: -20°C (-4°F) to +60°C (+140°F); RH <= 95%

Exceeding the transport and storage temperature range may result in damage to the liquid crystal display and the keypad of a REF 4580 MICRO-PACE.

MICRO-PACE ACCESSORIES

Additional or replacement accessory items for the REF 4580 MICRO-PACE are available. Contact the company for more detailed information.

Model 4830	Pace Line Autoclavable Adapter with Universal Connector at patient end. Length 10 inches (25.4 cm).
Model 4840	Pace Line Autoclavable Adapter with Female Redel® Connector at patient end.
REF 4580	Instruction Manual
REF 4580	Soft pack Carrying Case

DISCLAIMER – This Instruction Manual supersedes any and all manuals and marketing materials.

Trademarks

MICRO-PACE™ is a trademark of Pace Medical, Inc.
 AccuPace™ is a trademark of Pace Medical, Inc.
 Pace Line™ is a trademark of Pace Medical, Inc.
 Pace Loc™ is a trademark of Pace Medical, Inc.
 Redel® is a registered trademark of Lemo SA.

END OF USE - PRODUCT DISPOSAL

For disposal of a REF 4580 MICRO-PACE, it is recommended that the user return the device to the manufacturer for proper handling and recycling of its components - see Service on page 40.

INTERNATIONAL CLASSIFICATIONS AND CERTIFICATIONS

The REF 4580 Dual-Chamber, DDD, Temporary Cardiac Pacemaker has been tested to ensure compliance with the intent of Council Directive 89/336/EEC for Electromagnetic Compatibility.

Compliance was demonstrated to the following specifications as listed in the Official Journal of the European Communities:

EMC Directive 89/336/EEC:

EN 55011	Class B Radiated Emissions
EN 61000-4-3	RF Electromagnetic Field Immunity
EN 61000-4-2	Electrostatic Discharge Immunity

Applicable safety standards: IEC 601-1, IEC 601-2-31. The REF 4580 is classified as a Type CF defibrillation-proof applied part and bears the international symbol identifying it as such shown below:



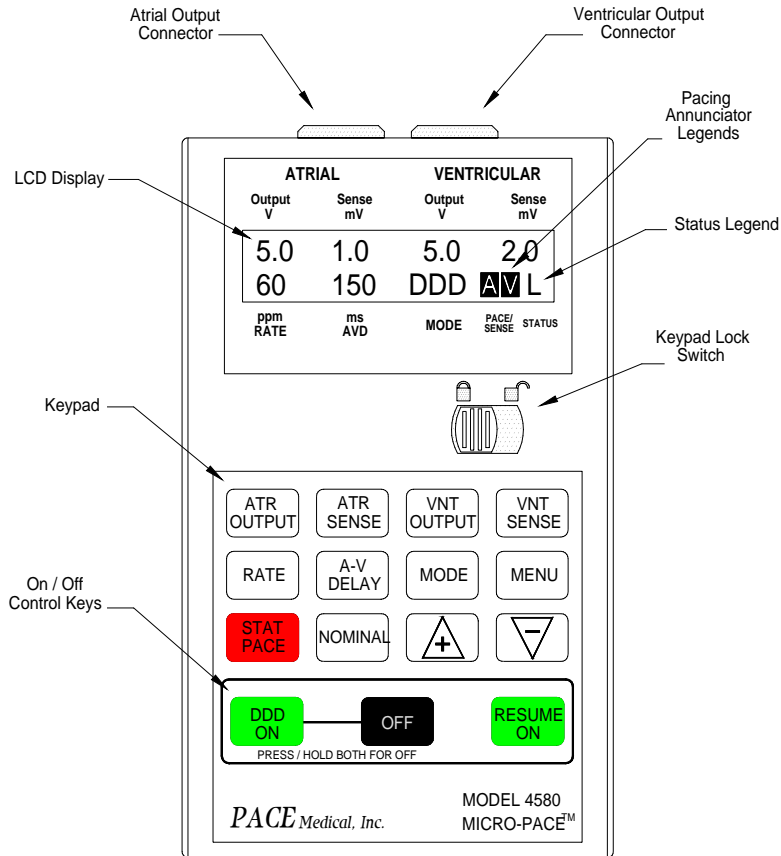
The REF 4580 bears the CE Mark to indicate its compliance with the requirements of Annex I of Council Directive 2007/47/EC, known as the "Medical Device Directive".



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REF 4580
DUAL-CHAMBER
TEMPORARY CARDIAC PACEMAKER



STORAGE

The carrying case of the MICRO-PACE provides considerable protection from accidental damage both during transport and while in storage. Try to select a storage location that is cool (about 20°C or 68°F) and dry. In no event should a REF 4580 be stored, even temporarily, in a location where the ambient temperature is either below -20°C (-4°F) or above 60°C (140°F). Damage to the liquid crystal display and keypad may result.

DO NOT store a MICRO-PACE for an extended period, with the batteries in place. Battery leakage may cause corrosion of the battery terminals and damage the electronics.

SERVICE

In the event a REF 4580 MICRO-PACE fails to function in accord with its specifications for any reason, it must be returned to Pace Medical, Inc., 391 Totten Pond Road, Waltham, MA 02451, USA or its Authorized European Representative, APC Medical Ltd., 68 Tewin Road, Welwyn Garden City, England for repair. Please enclose a letter or report detailing the problem encountered. If appropriate, please also enclose an ECG demonstrating the problem and detailed notations of the programmed settings of the MICRO-PACE at the time. **This is not a user serviceable product.** Telephone Pace Medical, Inc. at + 1 (781) 890-5656 or, if outside of the United States or Canada, APC Medical Ltd. at +44 (0707) 327641 for a return authorization number and for assistance or additional information.

WARRANTY

LIMITED WARRANTY FOR PACE MEDICAL, INC. AND ITS WHOLLY OWNED SUBSIDIARY, APC MEDICAL LTD., TEMPORARY CARDIAC PACEMAKERS.

The Company warrants its Temporary Cardiac Pacemakers to be free from defects in materials and workmanship for one year from the date of delivery when operated in accordance with the written Operating Instructions which accompany the equipment.

This Warranty extends to the original purchaser of the equipment only, and not to any subsequent purchasers.

The Company's obligations under this Warranty shall be limited to repair or replacement of a part or parts found to be defective during the Warranty period. All expendable items, such as Arm Straps, Extension Cables and Batteries are not covered by this Warranty.

The equipment as sold may embody design or performance modifications not reflected in applicable literature. However, the Company warrants that such modifications will not reduce the design performance of the equipment.

Any repair or calibration to the circuitry during the period of the Warranty will invalidate the terms of the Warranty unless performed by Company personnel.

LOW BATTERY INDICATOR AND BATTERY REPLACEMENT, CONTINUED.

CAUTION:

Failure to use the types of batteries recommended for use with this device; i.e. alkaline or lithium, may result in: 1) a failure to operate, 2) intermittent operation, or 3) a failure to provide a low battery warning period of a length considered adequate under all circumstances. Specifically, **do not use** Zinc-Air medical batteries in a MICRO-PACE.

POTENTIAL SYSTEM COMPLICATIONS

Complications which have historically been associated with cardiac pacing include, but are not limited to: lead dislodgment, lead failure, loss of capture, loss of sensing, pacemaker runaway, output failure, infection, component failure, inappropriate response to electromagnetic interference (EMI), and bizarre rhythms resulting from inadvertent programming errors; or in dual-chamber systems, arising as a consequence of connecting the leads incorrectly, or as a result of crosstalk.
















In cases of lead dislodgment or failure, the most common symptom is intermittent or complete loss of sensing and/or capture. Loss of capture can result from lead failure, exit block at the site of the electrode due to normal threshold rises or as a consequence of abnormal factors such as tissue damage adjacent to the electrode due to defibrillatory discharges, inappropriate application of electrosurgical devices, or infection, and loss of output as with a component failure or a simple failure to properly tighten the terminals of the pacemaker onto the lead pins or wires. Loss of sensing may occur for reasons similar to those listed for loss of capture. In addition, the presence of environmental EMI can cause pacemaker behavior that mimics loss of sensing on the one hand and triggered pacing or tracking behavior on the other with the detected signals being interpreted as valid P-waves. Pacemaker "runaway" rarely occurs in modern devices. It is defined as an excessive rate unintended and not anticipatable from the programmed or fixed settings of the pacemaker. This definition limits the cause to component failure and the event itself has been largely eliminated by way of circuit design. Output failure may result from component failure or lead failure manifesting itself as a loss of an effective pacing stimulus. Finally, simple programming errors can produce any or all of the symptoms which have been described and, once identified, are just as easily corrected.

CAUTION:

DO NOT USE a MICRO-PACE, if it has been dropped onto a hard surface. Regardless of whether the device appears damaged, hidden damage may have occurred which may later cause device malfunction. Factory evaluation and service is recommended. See Service, page 40.

Figure 1

KEY TO PANEL CONTROLS AND DISPLAY DESCRIPTION OF CONTROL PAD KEYS

	Press to activate atrial output. Change value using + and – arrow keys. Confirmation is not required.
	Press to activate atrial sensitivity. Change value using + and – arrow keys. Confirmation is not required.
	Press to activate ventricular output. Change value using + and – arrow keys. Confirmation is not required.
	Press to activate ventricular sensitivity. Change value using + and – arrow keys. Confirmation is not required.
	Press to activate pacing rate. Change value using + and – arrow keys. Confirmation is not required.
	Press to activate atrioventricular delay. Change value using + and – arrow keys. Confirmation is not required.
	Press to activate mode select. Change value using + and – arrow keys. Following selection, press again to confirm.
	Press repeatedly to scroll through less frequently used parameters. Change values using + and – arrow keys. Confirmation is not required.
	Press to activate high output pacing in DDI mode. Confirmation is not required.
	Press to change all parameter settings of the programmed mode to their nominal values. Confirmation is not required.
	Scroll up through the optional values of parameters or settings for mode to make new selection.
	Scroll down through the optional values of parameters or settings for mode to make new selection.
	Energizes the device in DDD mode pacing nominal values.
	Press and hold the DDD ON and OFF keys simultaneously to turn off the device.
	Energizes the device pacing the previously selected mode and programmed values.

**TABLE 1 - REF 4580 MICRO-PACE
SUMMARY OF MODES AND PARAMETERS**

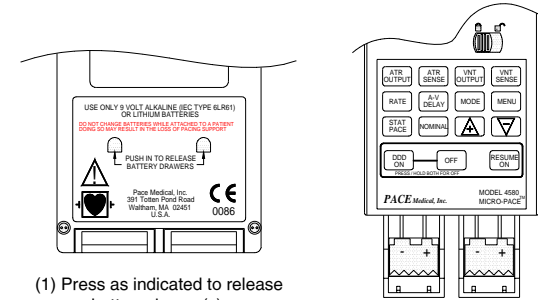
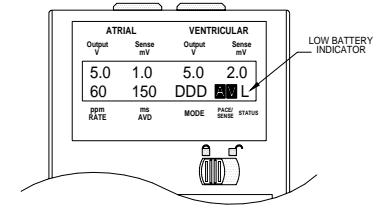
Modes/Parameters	Values	Nominal/STAT	Steps/Units
Modes	DDD, DDI, DVI, DOO, VDD, VVI, VVT, VOO AAI, AAT, AOO	---- / DDI	N/A
Basic Rates ¹	30 – 200	72(60) / 60	1 ppm
Rapid Stimulation ¹	60 – 800	100 / ----	10 ppm
Pulse Amplitude ² (A&V)	0.1 – 3.0 3.0 – 6.0 6.0 – 10 10 – 14	5.0 / 10	0.1 V 0.2 V 0.5 V 1.0 V
Pulse Width ³ (A&V)	0.05 – 2.0	1.0 / 1.5	0.05 ms
Sensitivity ⁴ (Atrial) (Ventricular) (Atr & Vnt) (Atr & Vnt) (Atr & Vnt)	0.2 – 3.0 0.5 – 3.0 3.0 – 6.0 6.0 – 10 10 – 20	1.0 / 1.0 2.0 / 2.0	0.1 mV 0.1 mV 0.2 mV 0.5 mV 1.0 mV
Atrial Refractory Period ¹ DDD, DDI, VDD* AAI AAT	196 – 500 196 – 500 250 – 500	250 / 250 400 / ---- 400 / ----	AutoPgmd AutoPgmd AutoPgmd
Ventricular Refractory Period ¹ DDD, DDI, VDD DVI, VVI VVT	196 – 500 196 – 500 250 – 500	325 / 325 325 / ---- 325 / ----	AutoPgmd AutoPgmd AutoPgmd
AV Delay ¹	50 – 400	150 / 150	AutoPgmd
Max. Tracking Rate ¹	90 – 230	120 / ----	AutoPgmd
Vent. Blanking Period	10 – 50	30 / 30	1.0 ms
Vent. Safety Pacing	Enabled	Enabled	N/A
PV Delay ¹	AVD - 25ms	125 / ----	AutoPgmd
PMT Term. Algorithm	10 beats ≥ MTR	10 beats ≥ MTR / --	N/A
PVC Response	DVI on PVC	DVI on PVC / ---	N/A

Specifications @ 20°C ± 2°C with 500 Ohm ± 1% load:

1 = ± 5% 2 = the greater of ±10% or 0.05V 3 = ± 10% 4 = ± 20%

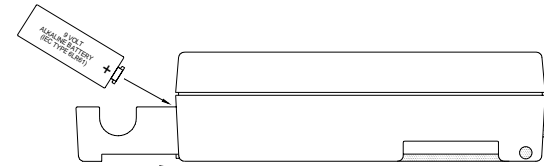
* Post-Ventricular Atrial Refractory Period (PVARP)

LOW BATTERY INDICATOR AND BATTERY REPLACEMENT, CONTINUED.



(1) Press as indicated to release battery drawer(s).

(2) Withdraw battery drawer(s).



(3) Insert battery as indicated observing polarity and slide the battery door closed. **Ensure battery door latch clicks shut.**

CAUTION:

The MICRO-PACE is designed to suspend operation when the battery voltage reaches a level beyond which safe operation can no longer be assured. The user should check for the low battery warnings routinely, and replace the batteries at the first indication of low battery. Abrupt loss of pacing may occur, if the low battery warnings are ignored.

CARE AND USE OF THE EXTENSION CABLES , CONTINUED.

Disinfection and Sterilization of Extension Cables

Before use, the MICRO-PACE extension cables may be cleaned with 70% isopropyl alcohol. Air dry thoroughly. Automated cleaning machine cycles have been tested and approved for use. Refer to Pace Medical / APC Medical Technical Bulletins for details. Have a qualified technician test cable continuity. Sterilize by steam autoclaving at 121°C for 30 minutes, additional autoclave cycles have been tested and are approved for use. Refer to Pace Medical / APC Medical Technical Bulletins for details. DO NOT USE EtO or gamma irradiation to sterilize these cables.

LOW BATTERY INDICATOR AND BATTERY REPLACEMENT

The REF 4580 MICRO-PACE is designed so that it may be operated on one or two 9 volt alkaline batteries (IEC Type 6LR61) or equivalent 9 volt lithium batteries. It is recommended that two fresh batteries be installed for each new patient. **When installing batteries, make sure the battery drawer latches click shut.**

USE ONLY FRESH 9 VOLT ALKALINE (OR LITHIUM) BATTERIES

A typical MICRO-PACE pacemaker will operate at nominal DDD settings with 500 Ohm output loads for about 14 days before triggering a low battery warning with two Duracell Model MN1604 or Eveready ENERGIZER Model 522 alkaline batteries installed. Single battery operating time is about half of that. Lithium batteries will last about twice as long as alkaline. Use of batteries with different physical dimensions from that of the recommended batteries may result in erratic, or no, pacing output. **It is recommended good practice to always place the REF 4580 MICRO-PACE into service with two fresh batteries.**

Low battery condition in the REF 4580 MICRO-PACE is indicated by a flashing "L" in the lower right-hand corner of the status display. In addition, once per minute a beep and the display message, "WARNING: Replace 9 Volt Battery" will occur. With two alkaline batteries installed, the REF 4580 will continue to operate satisfactorily for a minimum of 24 hours while pacing at or below 70 ppm with nominal outputs. Should a low battery indication occur during use, temporarily replace the REF 4580 MICRO-PACE with another unit while the batteries are being changed. *Do not change the batteries while attached to a patient, doing so may result in the loss of pacing support.* When connecting the REF 4580 to the patient, follow the *Lead Connection* instructions on page 22. Low batteries should be changed without delay. The batteries should be removed when the device is stored for extended intervals.

GENERAL DESCRIPTION

The REF 4580 MICRO-PACE™ Dual-Chamber, DDD, Temporary Cardiac Pacemaker is a software programmable, internally-powered pulse generator designed for multi-mode, multi-parameter operation. It is capable of operating in all of the commonly accepted pacing modes from ventricular or atrial asynchronous (VOO or AOO) to AV Universal (DDD). Every pacing parameter which may need to be adjusted to suit the needs of a specific patient, can be adjusted, not only over a broad range, but in increments, fine or coarse, which are more physiologically or diagnostically appropriate to that portion of the range of values. Programmable parameters, among others, include: rate, sensitivity, pulse amplitude, pulse width, refractory period(s), AV delay, maximum tracking rate, blanking period, and rapid stimulation. Additional standard pacing parameters are provided as non-programmable features.

The REF 4580 MICRO-PACE has several important features, including: 1) a basic programmable rate as high as 200 ppm in any mode, 2) constant voltage output, 3) a non-volatile memory function to allow the storage and subsequent retrieval of previously programmed mode parameters, 4) the ability to employ the device as a rapid atrial stimulator from any programmed mode, 5) a maximum output capability of 14 volts on both channels, 6) a keypad "lock" to prevent unintended changes, 7) a means to suspend output to check on underlying rhythm, 8) a dual-chamber, non-competitive, high output STAT PACE from any mode, 9) an enhanced atrial sensitivity adjustable to 0.2 millivolts, 10) a "resume" function which allows prompt recovery of the last programmed mode and parameter settings when the device is turned on using the RESUME ON key, 11) enhanced low battery indicators, and 12) recessed output connectors.

The case of the REF 4580 MICRO-PACE is fabricated of a durable plastic case incorporating an integral IV pole hanger, which can be configured to accommodate an arm strap allowing the device to be attached to the patient. See page 4. A sealed keypad is used to turn the device on and off, and to access and perform all functions of the pacemaker. A continuously active liquid crystal display (LCD) provides the means for verifying program settings and changes, and for conveniently monitoring operation while in use.

A REF 4580 MICRO-PACE is small and light and may be worn comfortably by an ambulatory patient. The MICRO-PACE along with its batteries, cables and instruction manual is supplied in a padded carrying case. When not in use, it is recommended that the MICRO-PACE always be stored in its carrying case, with batteries removed, to protect it from accidental damage and potential battery leakage.

Finally, the REF 4580 MICRO-PACE is fully electrically isolated. The circuit is protected against damage due to normal cardioversion and defibrillatory discharges, and the risk of output inhibition caused by detection of environmental EMI is limited by special shielding and circuit design. Pacemaker "runaway" is prevented by special rate limiting circuitry.

WARNING:

As with any critical-care medical device, it is of the utmost importance that a REF 4580 and its extension cables be maintained in excellent condition. A REF 4580 which shows evidence of damage, defect or failure to operate in accord with any of its specifications should be promptly removed from service and returned to the company for repair and thorough retesting. Damaged extension cables should be promptly replaced. Serious adverse affects may be associated with the continued operation of an impaired medical device.

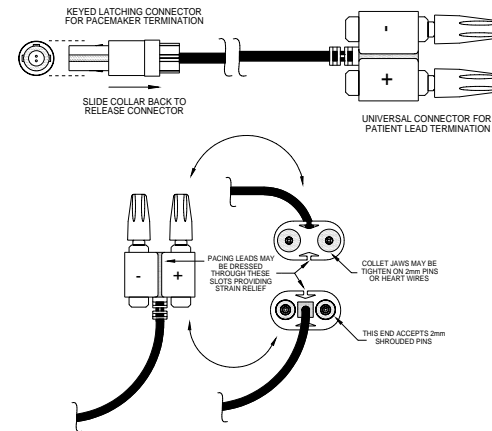
CARE AND USE OF THE EXTENSION CABLES

Each MICRO-PACE is supplied with two re-usable and sterilizable extension cables which permit the user to locate the pacemaker up to eight feet away from a patient. One of the cables (Model 5265A) is labeled "Atrium"; the other cable (Model 5265V) is labeled "Ventricle". This aids the identification of the cables during dual-chamber pacing procedures. The proximal end of the cable is a molded connector with a Redel® P-Series plug. The plug inserts directly into the output receptacles of a REF 4580 MICRO-PACE and locks into place. The universal connector on the distal end allows the connection of heartwires (or unprotected male pin connectors) and 2mm protected (shrouded) pin connectors.

Instructions for Use

See the LEAD CONNECTION information on page 22 for specific instructions regarding the attachment of the REF 4580 to the patient lead system. To connect heartwires (or other leads with unshielded pins), unscrew the caps of the collet terminals, insert each wire or its pin, and re-tighten securely, but only finger-tight. Observe polarity. To connect 2mm protected pin safety plugs from a temporary pacing catheter, insert each connector into its corresponding safety socket and push firmly into place. Observe polarity. Draw the wire adjacent to the plug up through the catch (PACE LOC™) on the side of the multi-purpose connector block. This is intended to help secure the safety plug connector in its socket.

After connecting the patient's leads to the extension cables, plug each extension cable into the appropriate (atrial or ventricular) output on the pacemaker, until it locks in place. See page 22. Check to see if the cable is securely locked in place by gently pulling back on the cable itself, not the plug. The plug and receptacle are keyed, and the cable can only be inserted with proper polarity. To remove the extension cable, pull back on the "collar" of the plug on the extension cable. The plug should release easily.



SENSING CIRCUITRY AND THE EFFECTS OF DEFIBRILLATION, EMI, AND ELECTROCAUTERY / ELECTROSURGICAL EQUIPMENT, CONTINUED.

If a procedure involving the use of EC / ES equipment is planned on a patient wearing a MICRO-PACE, it is further recommended that such use be limited either to short bursts or that the MICRO-PACE be programmed to a non-sensing mode during the procedure. In either case, it is important that the patient be monitored continuously and that the precautions previously noted be rigorously observed during the entire course of the procedure.

Two-way radios and some cellular telephones are known to have the ability to interfere with the proper operation of temporary cardiac pacemakers functioning in a sensing mode. Such devices should not be used in the immediate vicinity of a patient with a pacemaker.

Magnetic resonance imaging (MRI) equipment produces very powerful magnetic pulses. These can interfere with and/or damage the circuitry of temporary cardiac pacemakers. Use within or near such equipment should be avoided.

Defibrillation protection - A REF 4580 MICRO-PACE is designed to tolerate defibrillator discharges of up to 400 Joules across the body of a patient having leads connected to the device. However, if time permits, it is recommended that the REF 4580 be disconnected from the patient during defibrillation.

NORMAL MAINTENANCE OF THE REF 4580 MICRO-PACE

A REF 4580 MICRO-PACE is both durable and water resistant, but **it is not water-proof**. If cleaning is required, it is recommended that a soft cloth moistened with 70% isopropyl alcohol be used to wipe the device. No unusual maintenance is otherwise required.

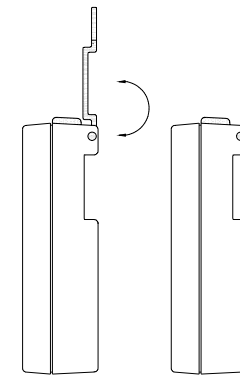
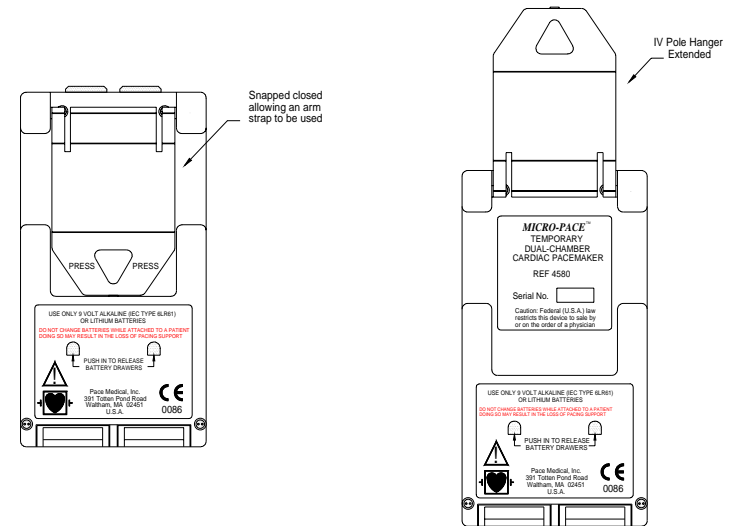
Do not expose the REF 4580 MICRO-PACE to ethers, acetone, or chlorinated solvents as these may damage the case or labels.

Keep an adequate supply of batteries on hand. At least some of this supply should be kept with the MICRO-PACE in its carrying case.

CAUTION:

Do not attempt to sterilize a MICRO-PACE using steam autoclaving, ethylene oxidegas (EtO), ultrasonics or gamma irradiation. Do not immerse a MICRO-PACE in cleaning or sterilizing solutions. Such procedures can seriously damage the device.

IV Pole Hanger / Arm Strap Orientations



Side View

CAUTION:

When handling indwelling leads, the terminal pins or exposed metal conductive elements must not be touched or allowed to come into contact with electrically conductive or wet surfaces.

Cardiac pacing leads and heartwires provide a direct electrical pathway to the heart. Strict attention to electrical safety practices must always be observed when performing cardiac pacing in the presence of line-powered monitoring or other support equipment as even minute alternating leakage currents flowing through the heart may induce ventricular fibrillation.

It is recommended that attending health care professionals discharge any static electricity by touching a large metal or conductive, grounded surface prior to touching the patient or patient cabling. Also neutralize any static electricity from the patient by touching the patient away from the cardiac leads.

When clinically indicated, supplemental monitoring of a patient should be considered during temporary cardiac pacing.

If a REF 4580 has been subjected to conditions of transport or storage at temperatures below 10°C (50°F) or above 40°C (104°F), it should be allowed to sit at room temperature (about 20°C or 68°F) for an hour before being placed in use on a patient.

KEY TO STATUS INDICATORS

- | | |
|---|--|
| A = atrial output pulse | V = ventricular output pulse |
| P = atrial channel sensing event | R = ventricular channel sensing event |
| L = low battery condition (flashing) | N = interference detected |
| W = device is performing Wenckebach in presence of high atrial rate. | B = device is performing 2:1 or greater block in the presence of a high atrial rate (dual-chamber). |
| S = device is performing ventricular safety pacing. | • = a sense event is occurring in the refractory alert period (see page 12 for discussion). |

Figure 2.

DETERMINATION OF SENSING THRESHOLD

This test can only be performed if the patient has an intrinsic rate above the lowest rate of the pacemaker (30 ppm). Set the MICRO-PACE as follows, taking any special requirements of the patient into account:

1. With mode set to VVI and output set to minimum, set sensitivity to any value which produces consistent sensing.
2. Reduce the rate to 10 ppm below the patient's intrinsic rate.
3. Slowly decrease sensitivity (increase setting value) until sensing is lost and a pacemaker output pulse is delivered.
4. Increase the sensitivity to inhibit the output pulse. This sensitivity value is the maximum amplitude of the detected R-wave described in millivolts.

This procedure may be repeated for an atrial lead using the AAI mode or DDD mode, if the device is tracking P-waves and effectively operating in the VDD mode. Reduce atrial sensitivity until loss of sensing is demonstrated by: 1) pacemaker inhibition (intact conduction) or 2) AV Sequential pacing (CHB).

SENSING CIRCUITRY AND THE EFFECTS OF DEFIBRILLATION, EMI, AND ELECTROCAUTERY / ELECTROSURGICAL EQUIPMENT

The sensing circuit of a typical REF 4580 MICRO-PACE is designed to be maximally sensitive to signals of cardiac origin while eliminating, to the extent practical, interference from other sources; ex. biopotentials (EMG) and environmental electromagnetic (EMI) interference. However, since the more common and abundant frequencies associated with myocardial depolarization are in the frequency range of 50 - 60Hz, which is all too common otherwise, it is clear that the process of proper signal discrimination cannot be absolutely assured in all circumstances. Some unwanted signals clearly will be sensed and, thus, all cardiac pacemakers are provided with additional means by which the potential negative effects resulting from such detection are substantially limited. Specifically, in the REF 4580 MICRO-PACE, any detected signal with a repetition rate equal to or less than 10Hz will cause pacemaker inhibition (or triggering depending upon the mode programmed). Namely, signals with the right frequency content which also repeat very slowly could be cardiac in origin and a stimulus is withheld in inhibited modes to avoid the potential for competition. On the other hand, if the signal has a repetition rate in excess of 10Hz, a pacemaker programmed to VVI will operate at its base ventricular rate, asynchronously, while it continues to sample for the presence of noise.

Electrocautery (EC) or electrosurgical (ES) devices are capable of generating very powerful electromagnetic fields which can induce damaging currents in microelectronic devices. Further, it is also possible to induce fibrillatory currents in pacing leads implanted in a patient by this means. The software-controlled circuits of the REF 4580 MICRO-PACE may be seriously damaged by the use of electrocautery / electrosurgical devices within six inches of the device or the leads connected to the device.

SAFETY FEATURES

Pre-programmed safety interlocks, timed program reverts and flashing data displays all serve the very important function of minimizing the potential for and the effects of programming or electronic errors. In addition to the self-diagnostic performed when the device is first turned on, which is described on page 21, the REF 4580 MICRO-PACE also maintains an on-going surveillance of critical components and operations. In the event an abnormality or failure is detected, an alert or warning is provided and, in some instances, the pacemaker automatically adjusts to a back-up mode of operation. For example, in the event that such monitoring detects an error attributable to the random access memory (RAM) of a MICRO-PACE, the device will revert to dual-chamber asynchronous operation at nominal values for rate and output, regardless of whether the previously programmed mode was dual-chamber or single-chamber. This is accompanied by a flashing error display identifying the problem.

In the event of certain failures involving the software and some key hardware elements, warning displays will flash as an alert to the inappropriate function. Where possible, pacing is maintained with dual-chamber asynchronous output. However, proper function usually cannot be assured and continued use is not recommended, even if the error condition can be cleared. The MICRO-PACE should be removed from service and returned to the company for evaluation and possible repair.

DETERMINATION OF CAPTURE THRESHOLD

With the MICRO-PACE connected to the lead(s) and pacing the patient, set the controls as follows taking any special requirements of the patient into account:

1. Set the mode to VVI
2. Set the rate 10 ppm above the patient's rate.
3. Set the ventricular output to 2.5 V (higher if needed).
4. Slowly decrease output until capture is lost.
5. Slowly increase output until capture is regained. This is the capture (or stimulation) threshold.
6. Increase the output to provide an ample margin of safety for capture; the greater of 5.0 V or 3 - 4X the threshold.

If pacing will continue for several days, it may be appropriate to retest the lead periodically (daily) as acute thresholds can rise dramatically. It is recommended that the output be kept at 5V or above unless special circumstances with the patient necessitate otherwise.

For an atrial lead, the above may be repeated in an appropriate mode; ex. AAI or DDI with the atrial lead connected to the atrial output terminals, in addition.

CAUTION: AAI mode should not be used on a patient with complete heart block (CHB).

INDICATIONS, CONTRAINDICATIONS AND WARNINGS

Indications

The REF 4580 MICRO-PACE temporary pacemaker may be used in any clinical situation in which the use of a temporary pacemaker on a patient provides therapeutic or diagnostic value, or serves a prophylactic purpose. Specifically, indications for the use of temporary cardiac pacemakers include, but are not limited to, the following:

- intermittent or complete heart block;
- sinus bradycardia, symptomatic sinus bradycardia;
- surgically-induced heart block;
- sick sinus syndrome;
- bradycardia with congestive heart failure;
- atrial and/or ventricular arrhythmias;
- cardiac arrest;
- support, management, and evaluation of a patient prior to permanent pacemaker implantation;
- support during permanent pacemaker replacement;
- cardiac complications during invasive or surgical procedures;
- support during cardiac surgery;
- acute myocardial infarction complicated by heart block;
- rapid stimulation for the treatment of atrial tachyarrhythmias.

Although the intended uses of a REF 4580 MICRO-PACE are primarily therapeutic and prophylactic, the ability to extensively program the constant voltage output and pulse width allows it to be used to determine capture thresholds of temporary and permanently implanted lead systems. However, Pace Medical recommends the use of a Pace Medical AccuPace™ Pacing Analyzer.

Contraindications

There are no known contraindications to the use of temporary cardiac pacing as a therapeutic or prophylactic modality. Certain relative contraindications can exist, however, if a particular pacing mode or parameter is applied in inappropriate circumstances. For example, in the presence of atrial fibrillation, atrial pacing and/or sensing modes will not be effective in controlling atrial activity and carry the risk of inappropriately responding to detected atrial fibrillatory waves. Therefore, there is a relative contraindication against the application of such modes in patients who demonstrate chronic, persistent atrial fibrillation. Additional noteworthy examples include, but are not limited to: 1) atrial pacing in the presence of certain AV conduction disorders, and 2) the application of any asynchronous mode of pacing such that competition with an intrinsic rhythm results.

INDICATIONS, CONTRAINDICATIONS AND WARNINGS, CONTINUED.

WARNING:

The REF 4580 MICRO-PACE temporary pacemaker is a sophisticated electronic device capable of complex modes of operation, and having functions and characteristics which may be unfamiliar to medical personnel whose experience with the varied techniques of cardiac pacing may be limited.

Before handling an external pulse generator, patient cable(s), or indwelling lead(s), steps should be taken to equalize the electrostatic potential between the user and the patient; e.g. by touching the patient at a site remote to the pacing lead.

To prevent pacing into the vulnerable period of the T-wave, turn the REF 4580 ON and set the atrial and ventricular output amplitudes down to minimum amplitudes before connecting the REF 4580 to the patients lead system.

When using extension cables with the MICRO-PACE, always connect the extension cables to the pulse generator prior to making the connections between the extension cables and the pacing leads heartwires at the patient.

PROGRAMMABLE MODES AND PARAMETERS

Single-Chamber Modes

AOO - Atrial asynchronous pacing

Atrial pacing is provided at the programmed rate regardless of intrinsic rhythm.

AAT - Atrial synchronous pacing*

Atrial pacing at the programmed rate is provided in the absence of intrinsic activity. Intrinsic activity occurring in the alert period will reset pacemaker timing and result in an output pulse being issued synchronously with the detected activity.

* In the REF 4580, the maximum triggering rate is limited to the lesser of 60,000 divided by the programmed refractory period, or 200 ppm.

AAI - Atrial inhibited pacing

Atrial pacing at the programmed rate is provided in the absence of intrinsic activity. Intrinsic activity occurring in the alert period will reset pacemaker timing to the beginning of the refractory period with inhibition of the output pulse.

VOO - Ventricular asynchronous pacing

Ventricular pacing is provided at the programmed rate regardless of intrinsic rhythm.

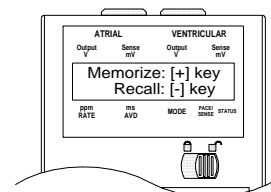
MEMORY

To speed the reprogramming process that may, in particular, be associated with dual-chamber pacing modes used in special applications, the REF 4580 MICRO-PACE has a non-volatile memory, allowing the storage of one set of parameter values per mode. Once stored, these parameter values can be repetitively recalled as needed. Parameter values stored in memory will be permanently retained, until a new set of values for a mode is stored over the old.

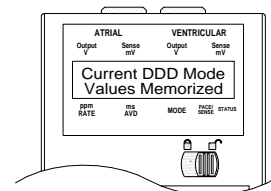
To enter parameter settings to memory, press the MENU key and obtain the display, "Memorize: [+] key / Recall: [-] key". All parameter values for the mode then programmed will be memorized, if confirmed by a press of the Up (+) arrow, as instructed.

To recall parameter settings from memory, press the MENU key and obtain the display, as described above, and press the Down (-) arrow, as instructed. Previously memorized values will immediately replace all other values then programmed.

MEMORIZE SEQUENCE

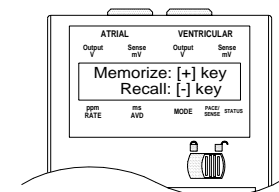


(1) Press the MENU key until above display message appears.

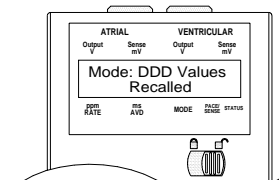


(2) Having pressed the [+] key to memorize existing settings for the current mode.

RECALL SEQUENCE



(1) Press the MENU key until above display message appears.



(2) Having pressed the [-] key to recall existing settings for the current mode.

PROGRAMMING, CONTINUED.

Rapid Atrial Stimulation

Rapid atrial stimulation mode is accessed by pressing the MENU key. Once the rapid stimulating mode is displayed, "Rapid = 100PPM / (Pacing = XXXPPM)", the rate may be varied from a low of 60 ppm to a maximum of 800 ppm by using the Up (+) or Down (-) arrows. Thereafter, rapid pacing can only be initiated by pressing and holding the RATE key. When this is done, the selected rate is activated and the mode automatically shifts to AOO.

While Rapid Stimulation is activated, the pacemaker will beep and continuously display the message, "WARNING: Pacing Rate = XXX PPM". When the RATE key is released, rapid pacing promptly ceases, the mode reverts to the previously programmed mode at the basic programmed rate, the display reverts briefly to "Rapid = XXX PPM / (Pacing = XXX PPM)", and the normal status display returns. The stimulation rate may be increased or decreased in steps of 10 ppm while performing Rapid Atrial Stimulation by use of the Up or Down arrows while pressing and holding the RATE key. Figure 14, below, describes the process of accessing and activating the Rapid Atrial Stimulation mode.

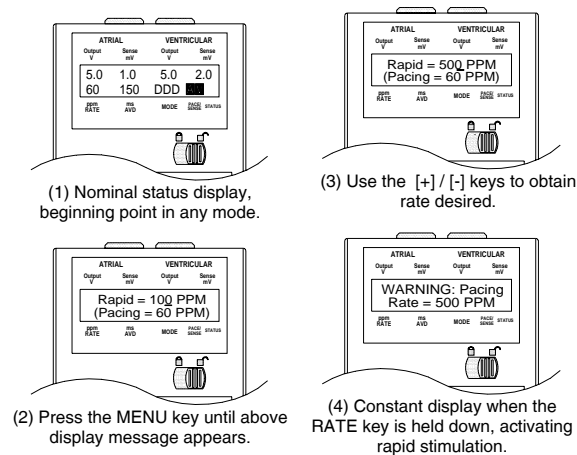


Figure 14

CAUTION:

Rapid stimulation of the atria carries with it the risk of precipitating ventricular tachy-arrhythmias, including fibrillation. The means for prompt resuscitation of a patient should always be close at hand when performing rapid atrial pacing.

PROGRAMMABLE MODES AND PARAMETERS, CONTINUED.

VVT - Ventricular synchronous pacing*

Ventricular pacing at the programmed rate is provided in the absence of intrinsic activity. Intrinsic activity occurring in the alert period will reset pacemaker timing and result in an output pulse being issued synchronously with the detected activity.

* In the REF 4580, the maximum triggering rate is limited to the lesser of 60,000 divided by the programmed refractory period, or 200 ppm.

VVI - Ventricular inhibited pacing

Ventricular pacing at the programmed rate is provided in the absence of intrinsic activity. Intrinsic activity occurring in the alert period will reset pacemaker timing to the beginning of the refractory period with inhibition of the output pulse.

Dual-Chamber Modes

DOO - Dual-chamber asynchronous pacing

Both chambers will be paced at the programmed rate regardless of the underlying rhythm.

DVI - AV sequential pacing

The capability for pacing is available in both chambers with sensing only in the ventricle. In the absence of ventricular activity, both chambers will be paced at the programmed rate and AV delay. Ventricular activity occurring during the ventricular alert period and before the atrial output pulse will inhibit both output pulses and reset pacemaker timing to the end of the AV delay. In the absence of ventricular activity during this period, an atrial output pulse will be provided at the end of the atrial escape interval and the timing for the AV delay will be initiated.

Intrinsic ventricular activity during the AV delay will inhibit the ventricular output pulse and reset pacemaker timing to the end of the AV delay. If intrinsic ventricular activity does not occur during the AV delay, a ventricular output pulse will be provided at the end of this interval, and a new atrial escape interval will be initiated. A ventricular blanking period occurs coincident with any atrial output pulse. This blanking period is intended to prevent detection of the atrial output pulse by the ventricular channel.

PROGRAMMING, CONTINUED.

Parameters (Rate, Output, Sensitivity, and AV Delay), Continued.

In the case of rate, output amplitude and sensitivity, there are legitimate reasons why one might want to permanently program an abnormally low or insensitive value. In the case of pulse width, however, no such case can be made. Consequently, permanent programming of pulse widths below 0.25 millisecond is not allowed. Temporary programming of values below 0.25 millisecond is permitted for up to 60 seconds. At the end of this period, the parameter will automatically revert to its nominal value. The return to nominal value is accompanied by a display message and by an audible beep.

The one minute time-out feature associated with low values for pulse width may be retriggered by making small changes in the programmed setting. Each time a change takes place, the timer or time-out feature is reset.

Automatic Programming of Parameters for High-Rate Dual-Chamber Pacing

To facilitate the programming of high dual-chamber pacing rates without requiring user intervention to adjust conflicting parameters such as AV delay and refractory periods, the REF 4580 MICRO-PACE will automatically shorten the refractory periods and then the AV delay, in that order, to satisfy the rate requirement. When the rate is reduced, the pacemaker will automatically restore the previously programmed values in the reverse order in which they were reduced. The maximum refractory periods in DDD mode will be 196 milliseconds and the maximum AV delay will be 54 milliseconds with the rate at 200 ppm. Automatic changes do not occur, if the last programmed value was equal to or less than these maximums. Additionally, the maximum tracking rate may conflict with the desired rate. To eliminate the conflict, the MTR will automatically be maintained at a minimum of 30 ppm above the programmed rate.

Menu

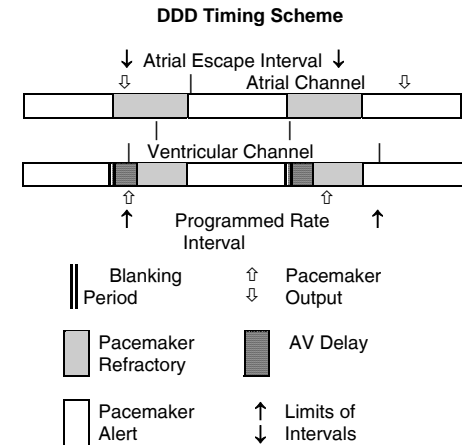
The MENU key provides access to special features and a number of operational parameters, the values of which are not routinely displayed, as they are of lesser overall importance. The first press of the MENU key causes the first option to be presented. Thereafter, additional parameters / options associated with the mode may be sequentially reviewed using individual key presses or, if a more rapid review of the parameters and their present settings is desired, by pressing and holding the MENU key.

To change the value of a menu parameter, press the MENU key until the desired parameter is displayed along with its present value, highlighted with a cursor. The Up (+) or Down (-) arrow is generally used to scroll through the options to the value desired. In some instances, the Up (+) or Down (-) arrow is used to enable or disable a function. The value or function above the cursor is automatically programmed and no further action is required. After sixty seconds, the status display returns accompanied by an audible beep. DDD mode sequence is depicted in Figure 13, alternate modes may have fewer screens based on parameter applicability.

PROGRAMMABLE MODES AND PARAMETERS, CONTINUED.

DDD - Dual-chamber atrial tracking

This mode allows for pacing and sensing in both chambers. In the absence of intrinsic activity, both chambers will be paced at the programmed rate. Intrinsic atrial activity during the atrial alert period will inhibit the atrial output pulse, terminate the atrial escape interval and begin the AV delay. Ventricular activity during the programmed AV delay will inhibit the ventricular output pulse, reset pacemaker timing to the end of the AV delay and initiate a new atrial escape interval. The absence of atrial activity during the atrial alert period will result in an atrial output pulse at the end of the atrial escape interval and AV delay timing will begin. Intrinsic ventricular activity occurring during the ventricular alert period will always recycle both channels, inhibit both output pulses, and reinitiate a new atrial escape interval. As with the DDI mode, a ventricular blanking period occurs coincident with any atrial output pulse.



PROGRAMMABLE MODES AND PARAMETERS, CONTINUED.

Basic Pacing Rate

The REF 4580 MICRO-PACE may be programmed from 30 ppm to 200 ppm in increments of 1 ppm in any single-chamber or dual-chamber pacing mode. Single-chamber modes have a nominal rate of 72 ppm. Dual-chamber modes have a nominal rate of 60 ppm. Rates below 45 ppm are intended for temporary diagnostic purposes. If an attempt is made to program them, a brief message, "Rate Below Typical Range", interrupts the process, after which the normal status display returns, allowing a further reduction of the rate.

The pacing rate is independent of battery voltage, providing a constant pacing rate as the battery voltage gradually declines to and beyond the point at which the voltage drop triggers the flashing low battery indicator, "L", on the status display. Timing functions of a MICRO-PACE are precisely determined by a crystal-controlled oscillator. As a consequence, there will be little difference between the rate of the MICRO-PACE as programmed and displayed and that as determined by independent measurement of the pacing interval. The REF 4580 MICRO-PACE is hardware rate limited to 250 ppm in all modes, except when the rapid atrial stimulation mode is activated. See page 31.

Pulse Amplitude

The pulse amplitude of the REF 4580 MICRO-PACE is programmable in steps of 0.1V from 0.1 to 3.0V, in steps of 0.2V from 3.0 to 6.0V, in steps of 0.5V from 6 to 10V, and in steps of 1.0V from 10 to 14V. If an attempt is made to program a value for pulse amplitude lower than 2.5V, a confirming message, "For Lower Output / Press [A (or V) OUT] Key", will be displayed. When the key is pressed, the display will change to "Output Below Typical Range", before returning to the normal status display. The pulse amplitude is independent of battery voltage, providing a constant output as the battery voltage gradually declines to and beyond the point at which the voltage drop triggers the flashing low battery indicator, "L", on the status display.

Pulse Width

Pulse width for the REF 4580 MICRO-PACE is programmable from 0.05 millisecond to 2.0 milliseconds in steps of 0.05 millisecond. Values less than 0.25 millisecond may only be programmed for 60 seconds at a time. A warning display will appear when an attempt is made to reduce pulse width below this level. At the end of 60 seconds, pulse width will revert to the nominal value, 1.0 millisecond. The pulse width is independent of battery voltage, providing a constant output as the battery voltage gradually declines to and beyond the point at which the voltage drop triggers the flashing low battery indicator, "L", on the status display.

PROGRAMMING, CONTINUED.

Parameters (Rate, Output, Sensitivity, and AV Delay), Continued.

The programming technique involving direct key selection and rapid scrolling of options of the most commonly changed parameters greatly facilitates the otherwise laborious process of programming the multiple parameters associated with more complex dual-chamber modes to suit each individual patient's requirements. To further aid this programming operation, important parameter values, once set, do not change with changes in mode.

If an attempt is made to program a parameter not typically associated with the operating mode, the MICRO-PACE rejects the key press with an audible warning tone and the brief display message shown in Figure 12.

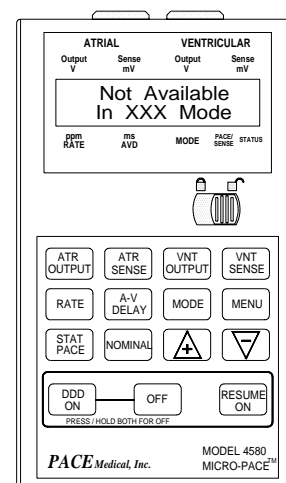


Figure 12.

Certain status display parameters require very specific action to access values that are generally clinically inappropriate or useful for test purposes only. In the case of pulse amplitude, the ATR OUTPUT or VNT OUTPUT key must be pressed when prompted by the status display in order to program abnormally low values. This serves as a warning to medical personnel that a range of values is being entered with limited clinical utility. A similar warning will be encountered when decreasing pulse width below 0.25 millisecond, or sensitivity above 5 mV or below 1 mV on either channel, but no additional key press is required.

PROGRAMMING, CONTINUED.

Parameters (Rate, Output, Sensitivity, and AV Delay)

Each status display parameter has its own dedicated key. To change a displayed value, press the appropriate key and a fixed cursor will appear beneath the value to be changed. Now use the Up (+) or Down (-) key to adjust the selected parameter value. The new value left in the status display will take effect immediately. Confirmation is not required. The cursor will disappear sixty (60) seconds following the last key press. More than one parameter value change may be made sequentially without waiting for the disappearance of the cursor. When programming is complete, lock the keypad to prevent inadvertent changes. The basic process just described is shown pictorially in Figure 11 for a change in rate.

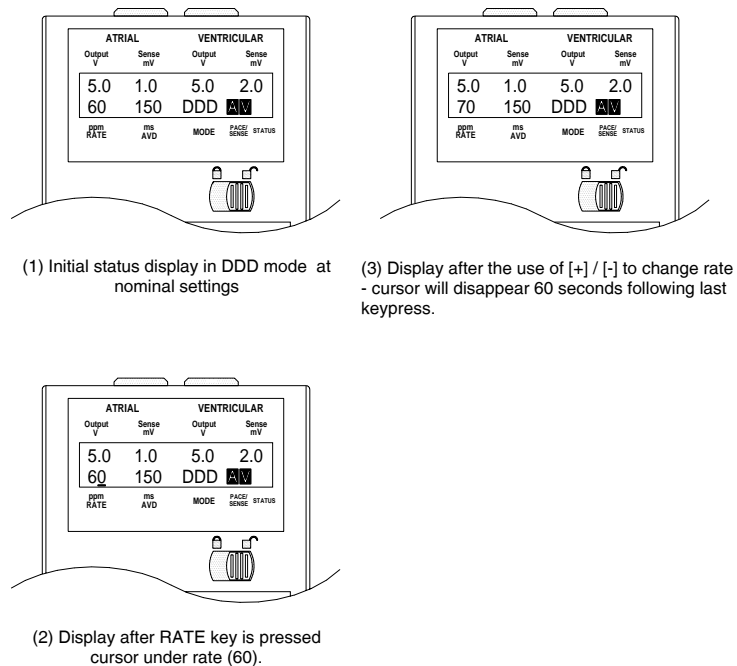


Figure 11.

PROGRAMMABLE MODES AND PARAMETERS, CONTINUED.

Sensitivity

Atrial sensitivity may be programmed from 0.2 to 20 millivolts. From 0.2 to 3.0 millivolts, the steps are 0.1 millivolt. From 3.0 to 6.0 millivolts, the steps are 0.2 millivolt. From 6.0 to 10 millivolts, the steps are 0.5 millivolt. And, between 10 and 20 millivolts the increment is 1.0 millivolt. Ventricular sensitivity may be programmed from 0.5 to 20 millivolts. From 0.5 to 3.0 millivolts, the steps are 0.1 millivolt. From 3.0 to 6.0 millivolts, the steps are 0.2 millivolt. From 6.0 to 10 millivolts, the steps are 0.5 millivolt. And, between 10 to 20 millivolts, the increment is 1.0 millivolt. The lower the numerical value, the higher the sensitivity. If an attempt is made to program a value greater than 5mV, the brief warning message, "Leaving Typical Sensing Range", will be displayed.

This broad range of programmable values on both the atrial and ventricular channels serves primarily two purposes: 1) oversensing or undersensing problems require great programming flexibility for successful management, and 2) unusually small incremental steps allow a physician to determine the amplitude of the signal as detected by the pacemaker with reasonable accuracy.

Knowing this, sensitivity may be programmed to a value which provides for a reasonable margin of safety. Unless the value so determined is smaller than that available with the nominal values, it is recommended that nominal values be used. The nominal values are generally adequate in the acute setting.

It is recommended that unnecessary changes from the nominal settings be avoided for sensitivity as they have been carefully selected as a compromise between the dual risks of over-sensing and undersensing. Sensitivity should not be increased without awareness that even modest changes may produce a dramatic increase in the risk of detecting unwanted interference. On the other hand, sensitivity should not be reduced on an acute lead with a modest R (or P) wave, nor in an ischemic patient with PVC's without appreciating that competition-induced arrhythmias may occur in any borderline sensing situation.

Refractory Periods

Pacemakers which operate in a sensing mode incorporate a feature known as the refractory period. Immediately following a pacemaker output pulse or a sensed event, the pacemaker ceases to be responsive to detectable signals for a pre-determined period. This prevents the pacemaker from detecting the terminal portion of the depolarization signal and, in some circumstances, the repolarization signal which may result in timing errors.

PROGRAMMABLE MODES AND PARAMETERS, CONTINUED.

Refractory Periods, Continued.

When the pacemaker is programmed to a dual-chamber sensing mode, there is a refractory period for each sensing channel. The pacemaker's ventricular refractory period is always initiated by a paced or sensed ventricular event. The total atrial refractory period is composed of two segments. Immediately following a paced or sensed atrial event, the atrial sensing amplifier becomes refractory for the AV delay or until a sensed ventricular event. Additionally, immediately following a paced or sensed ventricular event, the atrial sensing amplifier will become refractory for the programmed atrial refractory period. The atrial refractory period displayed is always the post-ventricular atrial refractory period (PVARP).

The refractory period is comprised of two parts: the absolute refractory period during which the detection of all signals is blocked, and the relative refractory (noise sampling) period during which signals are evaluated for repetition rate. Signals which occur at a frequency of 10Hz or more cause the pacemaker to revert to asynchronous operation at the programmed rate while continuing to monitor for the presence of noise.

Signals which occur at a frequency below 10Hz have no effect upon pulse generator timing, unless the signal is detected during the normal sensing (or alert) period following the noise sampling period. Should this occur, pacemaker output will be inhibited or triggered depending on the operating mode. See page 29 for *Automatic Programming of Parameters for High-Rate Dual-Chamber Pacing*.

AV Delay

The AV delay defines the time interval between an atrial output pulse and a ventricular output pulse. The available range of values for AV delay makes it possible to significantly shorten the time between atrial and ventricular events, if it is hemodynamically or electrophysiologically advantageous in a particular instance. The time may also be lengthened to allow for inhibition of the ventricular output pulse in those individuals without significant AV conduction defect. At any given rate, the AV delay plays an important role, as the value selected can improve, normalize or adversely influence stroke volume and, therefore, cardiac output.

The nominal value for AV delay is 150 milliseconds. See page 29 for *Automatic Programming of Parameters for High-Rate Dual-Chamber Pacing*.

PROGRAMMING, CONTINUED.

Mode, Continued.

Rate, output and sensitivity values will not change with changes in mode. In certain circumstances, auto-programming is used to facilitate rapid change of conflicting parameters.

Each time a key is pressed and every time a parameter or mode changes on the display there is an audible tone (beep). Failure to make a selection or confirm a mode change within sixty seconds of a key press or the pressing of any key other than MODE or an Up (+) or Down (-) arrow will cause automatic cancellation of the attempt and reversion to the initial operating scheme. In that event, the message shown in Figure 10 will briefly appear on the display.

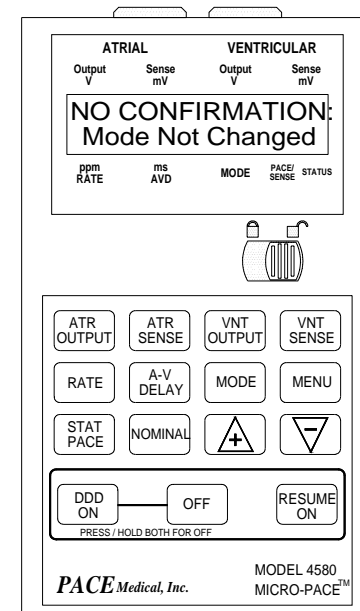


Figure 10.

PROGRAMMING

Mode

To program mode, press the MODE key and the display will change to "Current Mode: DDD / [MODE] Re-enters". In this instance, DDD is the presently programmed mode. A fixed cursor beneath "DDD" indicates preparation for a new mode selection. To select a new mode, press either the Up (+) or Down (-) arrow. If either is held, rapid scrolling of the options will occur. With the desired mode in the display, press the MODE key again to confirm the selection. This is the meaning of the phrase "[MODE] Confirms". The display now changes to confirm the new program and will briefly show "***CONFIRMED** / Mode is now XXX" before reverting to the normal operational display. This sequence of displays is shown in Figure 9, below, for a change from DDD to VVI mode.

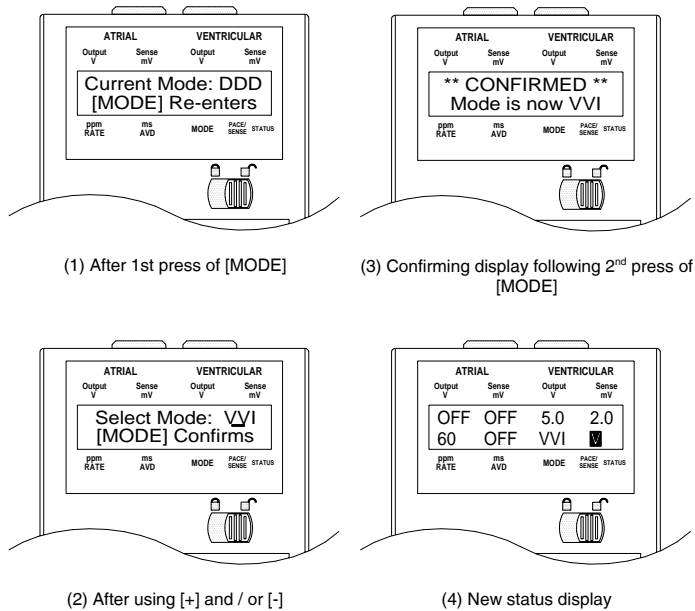


Figure 9

PROGRAMMABLE MODES AND PARAMETERS, CONTINUED.

Maximum Tracking Rate

The maximum tracking rate (MTR) is a variable parameter only in the dual-chamber tracking modes, DDD and VDD. This parameter has nothing whatsoever to do with the maximum triggering rate which may be achieved in the AAT or VVT modes, nor does it play any role in the rapid atrial stimulation mode.

Normal MTR behavior is electronic Wenckebach. However, both the MTR behavior and the maximum tracking rate itself, may be restricted or altered by values selected for the AV delay and the post-ventricular atrial refractory period, which together are called the total atrial refractory period (TARP). For example, if the values selected are, respectively, 175 milliseconds and 300 milliseconds, the upper limit of 1:1 P-wave tracking is determined by dividing 60 seconds (60,000 ms) by the sum of the two periods above, (TARP). In this

example, the result is a maximum tracking rate of 126 bpm. At faster atrial rates, only every other P-wave will be able to be sensed as the alternate P-wave will coincide with the TARP. This results in 2:1 pacemaker AV block. From this it will be seen that the TARP is the final determinant of the maximum sensed atrial rate and, thus, whether a desired maximum tracking rate behavior is possible. As an aid to the user, the display associated with the maximum tracking rate (Track Limit) in the menu identifies where 1:1 tracking stops and where Wenckebach begins and ends (and 2:1 block begins) based on the current device settings.

In the event the patient develops an atrial rhythm faster than the maximum tracking rate and the total ARP selected does not prevent it, the pacemaker will respond with electronic Wenckebach. Every detectable P-wave will be tracked with a progressively lengthening PV interval, while maintaining a stable V to V pacing interval. But, with a frequency which is entirely dependent upon the actual atrial rate being tracked, a P-wave will, from time to time, fall in the post-ventricular atrial refractory period and fail detection. The next P-wave in the series which is detected will be tracked instead, and the resulting V to V interval will be slightly longer than all the others. 2:1 block will be encountered when the P to P interval is equal to or less than the TARP (PV delay and post-ventricular atrial refractory period).

Because of the asynchrony that can occur at higher tracking rates and behaviors, the maximum tracking rate should be set to that value which most closely approximates the maximum normally occurring atrial rate in the patient, but which as a ventricular paced rate alone, will not produce angina or discomfort. Medical personnel should always be aware of the impact of the total atrial refractory period upon pacemaker performance at the high end of the normal rate range for the patient.

PROGRAMMABLE MODES AND PARAMETERS, CONTINUED.

Blanking Period / Crosstalk

When a REF 4580 MICRO-PACE temporary pacemaker is employed in the DVI, DDI or DDD mode, a brief period of refractoriness called the "blanking period" will momentarily occur in the ventricular sensing circuit coincident with the atrial output pulse. The length of the blanking period is variable from ten to 50 milliseconds. The nominal value is 30 milliseconds.

A blanking period is necessary to limit the risk of detection of the atrial output pulse by the ventricular sensing amplifier which, if detected, would result in ventricular output inhibition. This occurrence is commonly called "crosstalk". Crosstalk is easily identified in the clinical setting because only the atrial output pulse is present and the atrial pulse interval will measure as the sum of the programmed atrial escape interval (VA interval) plus the amount of the blanking period. In the absence of AV conduction or a native ventricular rhythm, the development of crosstalk can have catastrophic consequences. To help assure that this will not occur, ventricular safety pacing is always enabled (See page 16).

It is recommended that the blanking period not be programmed longer than that which is necessary to eliminate the occurrence of ventricular safety pacing. The nominal value, 30 milliseconds, is typically adequate.

Unnecessarily long blanking periods increase the risk that the intrinsic deflection of a native ventricular event, that part of the depolarization signal which is relied upon for appropriate sensing function, will coincide with the blanking period and fail detection. This will result in the delivery of a ventricular output pulse at the end of the programmed AV delay. If the AV delay has been programmed to less than 150 milliseconds or so, such an event occurring on a repetitive basis may not have deleterious clinical consequences. However, if

the AV delay has been programmed long in an attempt to facilitate normal AV conduction, an obligatory ventricular output pulse could then repetitively fall during the vulnerable portion of the cardiac cycle. Such circumstances increase the risk of ventricular arrhythmia in all patients, but that risk is particularly acute in electrically unstable patients.

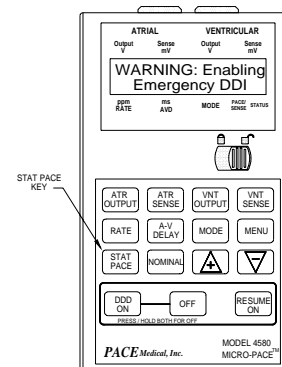
PACEMAKER OPERATIONS, CONTINUED.

Emergency Pacing

Pressing the STAT PACE key immediately changes the pacing parameters to STAT values (see Table 1) and changes the mode to Improved AV Sequential (DDI), regardless of the programmed mode. When [STAT PACE] is pressed, there is a brief message, "WARNING: Enabling Emergency DDI". Return of the status display showing the mode DDI and the changed parameter settings accompanied by an audible beep confirms completion of the command.

This high output mode is intended as one of the means which might be employed in an attempt to escape rapidly from a situation involving loss of capture with attendant asystole or bradycardia. Since this mode retains sensing, it will not be helpful, if the cause of an asystolic or bradycardic episode is inhibition of pacemaker output due to the presence of interference (environmental EMI) with a low repetition rate (less than 10 Hz).

Flashing "P" and/or "R" enunciators on the status display which are not matched by P-waves and/or R-waves on the patient monitor or ECG are a clear indicator of the latter problem. Selection of an asynchronous pacing mode (preferably VOO or DOO) or adjustment of sensitivity to a higher numerical value should promptly restore pacing and provide an opportunity to identify and remove the source of the interference.



CAUTION:

The use of high pulse amplitudes and long pulse widths has been associated with the spontaneous development of cross-stimulation related to lead position.

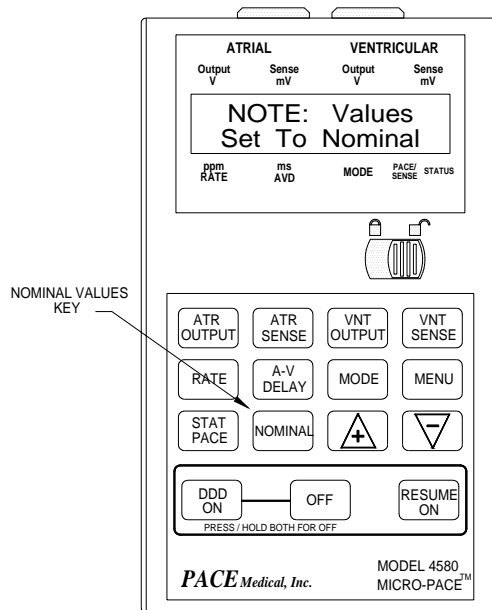
PACEMAKER OPERATIONS, CONTINUED.

Modified Bipolar Configuration

This configuration should be used with caution. To adapt an indwelling bipolar lead which has a single conductor fracture or electrode detachment, connect the positive (+) terminal to a skin electrode or wire placed subcutaneously. Connect the electrode which remains effective to the negative terminal. If both atrial and ventricular leads require modification, repeat this procedure for each; **DO NOT COMBINE THE LEADS INTO A SINGLE COMMON.** An increase in the blanking period may be required, depending upon the resulting lead orientation and the programmed atrial output and ventricular sensitivity settings.

Nominal (Values) Pacing

Pressing the NOMINAL key will immediately return all operational parameters of a REF 4580 MICRO-PACE to their nominal values in the mode then programmed. The confirmation message, "NOTE: Values Set To Nominal", appears briefly on the display. Note within the illustration below that the keypad lock switch is in the UNLOCKED position.

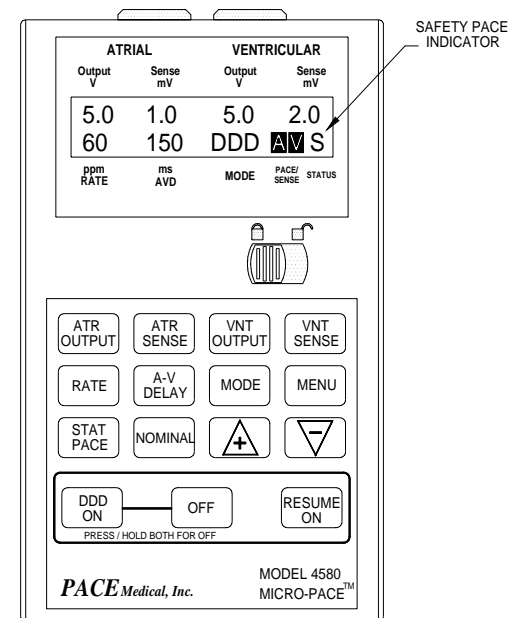


ADDITIONAL FEATURES / OPTIONS

Ventricular Safety Pacing

Ventricular safety pacing is designed to minimize the risk of inappropriate inhibition of the pacemaker's ventricular output pulse, if crosstalk occurs. This is accomplished by having the pacemaker alert for crosstalk for a short period of time after the blanking period. The duration of the crosstalk detection window is equal to 80 milliseconds minus the blanking period.

If any signal is sensed during the crosstalk detection window, the pacemaker is triggered to deliver a ventricular output pulse 120 milliseconds after the atrial output pulse. Normal sensing is maintained after the crosstalk detection window. Therefore, a sensed ventricular event that occurs between 80 and 120 milliseconds after the atrial output pulse will inhibit the pacemaker's ventricular output pulse, unless crosstalk was detected during the crosstalk detection window. In the REF 4580 MICRO-PACE, this function is always enabled. Safety pacing is indicated by the appearance of an "S" occurring coincidentally with the ventricular status enunciator, "V", in the extreme right-hand position on the display, following an initial "A".



ADDITIONAL FEATURES/OPTIONS, CONTINUED.

Inhibit Output

To momentarily inhibit the output of the REF 4580 MICRO-PACE while leaving the device on, e.g. to evaluate a patient's underlying rhythm, press the MENU key until the inhibit output option is displayed, highlighted by the cursor, then press and hold the ATRIAL OUTPUT and VENT OUTPUT keys simultaneously. To restore pacing, simply release the keys. Release of the keys will result in exit from the menu display and return of the normal status display. This sequence is shown by Figures 3 and 4, below.

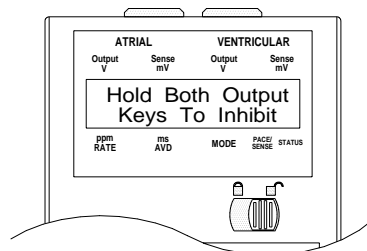


Figure 3.

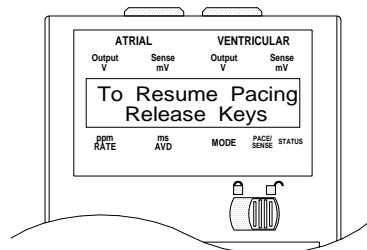


Figure 4.

CAUTION:

The underlying rhythm of a patient may also be assessed by simply turning the device off and then turning it back on using the RESUME ON key. However, each such instance abruptly ends pacing, and may result in a period of asystole in some patients. It is generally recommended that underlying rhythm first be assessed by slowly reducing the paced rate while in a sensing mode. The minimum rate of 30 ppm is provided to facilitate this approach.

PACEMAKER OPERATIONS, CONTINUED.

If ventricular output pulses are being delivered to the terminals of the MICRO-PACE, the Pace / Sense indicator will be flashing "V". Any sensed R-wave will be flashed as an "R". If an atrial sensing/pacing mode is selected, the letters "A" and "P" will appear, indicating pacing and sensing, respectively. In dual-chamber modes, combinations of all four may appear as flashing pairs of letters which describe exactly how the pacemaker is acting in each cardiac cycle. It is important to note that crosstalk may also be readily identified when it occurs by watching the enunciators. Specifically, the atrial enunciator will flash "A" followed almost instantly by an "V" flashing in the position of the ventricular enunciator and an "S" flashing in the right-hand enunciator position. This means that early AV interval noise is producing the safety pace response, and that noise is very likely to be attributable to ventricular detection of components of the atrial output pulse (crosstalk).

Lead Connection (see also Care and Use of the Extension Cables, page 36)

Normal Bipolar Configuration

The output connectors of the REF 4580 MICRO-PACE are two Redel® P-Series connector receptacles. Each is keyed so that the mating plug on the extension cable will only insert with proper polarity. The extension cables must be used to connect a REF 4580 to pacing lead connectors; i.e. heartwires or any exposed male pin connectors, or 2mm protected pin connectors. Each output receptacle is labeled as to its function. **To prevent pacing into the vulnerable period of the T-wave, turn the REF 4580 ON and set the atrial and ventricular output amplitudes down to minimum amplitudes before connecting the REF 4580 to the patient's lead system.** With the MICRO-PACE ON and output amplitudes set to minimum, connect the patient's pacing leads to the extension cable connector, and then connect the extension cables to the appropriate output receptacle as shown in Figure 3. Insert the plug connector of each extension cable until it locks into place. Check for proper insertion by gently pulling back on the cable, not the plug. Changes in the settings or the mode and pacing parameters may be made, following the instructions which begin on page 25.

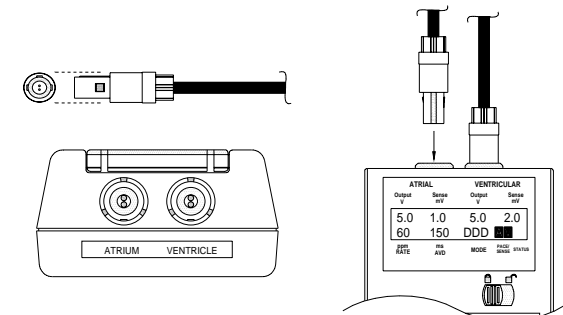


Figure 3

PACEMAKER OPERATIONS, CONTINUED.

DDD On, Resume On, Off, and the Lock Function, Continued.

If the battery is low at power on, a low battery warning message will initially appear accompanied by a beep (Figure 7). This message and beep will continue to occur every minute or so until the batteries are replaced.

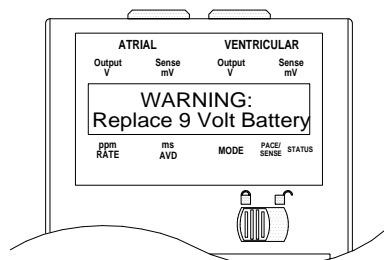


Figure 7.

The brief warning display in Figure 7 changes to the normal status display with a flashing "L" in the right-hand enunciator position as a constant reminder of low batteries (Figure 8).

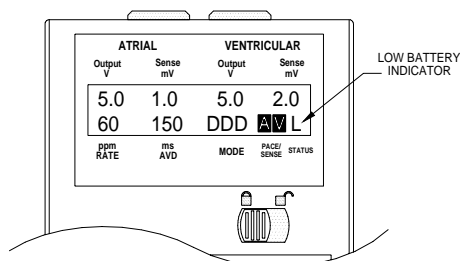


Figure 8.

A REF 4580 MICRO-PACE begins normal pacing operation immediately when turned on. **During the first eight seconds, however, use of the keypad is blocked while the software performs a self-diagnostic on its internal systems.** If a fault/error is found during this time, a warning will be displayed and the unit will automatically shut down. Otherwise, at the end of the self-diagnostic sequence, a beep will occur and normal keypad operation returns.

ADDITIONAL FEATURES / OPTIONS, CONTINUED.

PV Delay

The PV delay compensates for the differences, commonly observed in the clinical setting, between the PV interval which exists when P-waves are tracked to pace the ventricle and the AV interval which exists when both chambers are paced sequentially. When paced, the mechanical contraction of the atria lags behind the atrial output pulse. To compensate for this difference, the AV delay will automatically shorten by 25 milliseconds when it begins with a sensed P-wave, with the goal of having hemodynamically equivalent pacing and sensing intervals. The range of values for the PV delay is 25 - 375 milliseconds; always 25 milliseconds less than the programmed AV delay. This feature may not be independently programmed.

PMT Termination Algorithm

The REF 4580 MICRO-PACE temporary pacemaker is equipped with a special program for dealing with the common problem of endless-loop tachycardias; specifically, pacemaker-mediated tachycardias (PMTs). A PMT may result when a ventricular sense event occurs without a properly timed, preceding atrial paced or sensed event. These are usually premature ventricular contractions (PVC's).

In patients with VA conduction, a PVC may be followed by retrograde conduction to the atria resulting in a P-wave which is detected and tracked like any other P-wave which occurs during the normal sensing period. Typically, these P-waves occur early, resulting in an extended PV interval, producing yet another retrograde P-wave. Thus, the cycle tends to repeat itself with marked consistency, unless interrupted. Although a PMT is usually seen at the maximum tracking rate of the pacemaker, there are circumstances involving long VA conduction times in which sustained rates below the MTR are possible.

In a REF 4580 MICRO-PACE programmed to the VDD or DDD mode, the programmed PVC response option is always operative at the MTR. Namely, on the 10th consecutive beat of a sustained series above the MTR which fits the criteria for PMT, the ventricular output pulse will be followed by the PVC response, described below. If the first three beats following the PVC response are normal, the algorithm reverts to the 10 beat threshold. If the PVC response has failed to terminate the PMT, the attempt will be repeated again 127 cycles later. If the attempt is successful, normal DDD or VDD pacing will resume. If not successful, the attempt is repeated every 127 cycles until it is successful.

ADDITIONAL FEATURES / OPTIONS, CONTINUED.

PVC Response

In patients with retrograde conduction, detection of retrograde atrial events can result in pacemaker-mediated tachycardias (PMTs). One method of preventing PMTs is to program the post-ventricular atrial refractory period longer than the patient's retrograde conduction time. However, a long PVARP can artificially restrict the normal range of 1:1 AV synchrony. Since the majority of PMTs are initiated by PVCs, MICRO-PACE pacemakers offer a special PVC response intended to prevent PMTs.

When a MICRO-PACE is programmed to the VDD or DDD pacing mode, a protective response to the detection of a PVC is always enabled. The pacemaker will determine that a PVC has occurred, if it detects a ventricular intrinsic beat with no preceding paced or sensed atrial event. When this occurs, the pacemaker's atrial channel will be refractory immediately following any detected PVC. It will remain refractory until the delivery of an atrial output pulse. This response has been commonly referred to as "DVI on PVC".

PACEMAKER OPERATIONS

DDD On, Resume On, Off, and the Lock Function

In the REF 4580 MICRO-PACE, the on and off switches are located on the keypad. To turn the device on in the DDD mode at nominal parameter settings, press the DDD ON key. To turn it off, press and briefly hold the DDD ON and OFF keys simultaneously. To turn the device back on in the same mode and with the same parameter settings, use the RESUME ON key. An independent lock switch is used to render the keypad inoperative. It is recommended that the keypad always be locked when the patient is unattended. Note within the illustration below that the keypad lock switch is in the LOCKED position.

If the DDD ON key is used to energize the device, the mode will be DDD at nominal parameter settings (Figure 5).

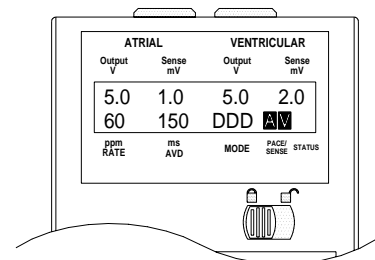


Figure 5.

If the RESUME ON key is used to energize the device, the mode and parameter values operative at the time the device was last turned off will immediately take effect (Figure 6).

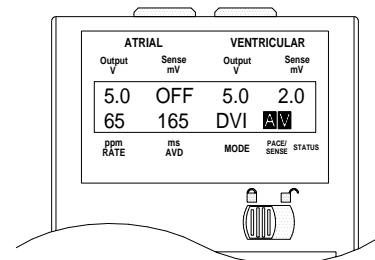


Figure 6.