

This manual is intended for use with devices containing software version 1.0. The software version in any device is disclosed in the Diagnostics display that is presented only at first power ON following battery insertion.

**INSTRUCTION MANUAL FOR
MICRO-PACE™ TEMPORARY PACEMAKER
MODEL 4570**

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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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Key to Panel Controls and Display

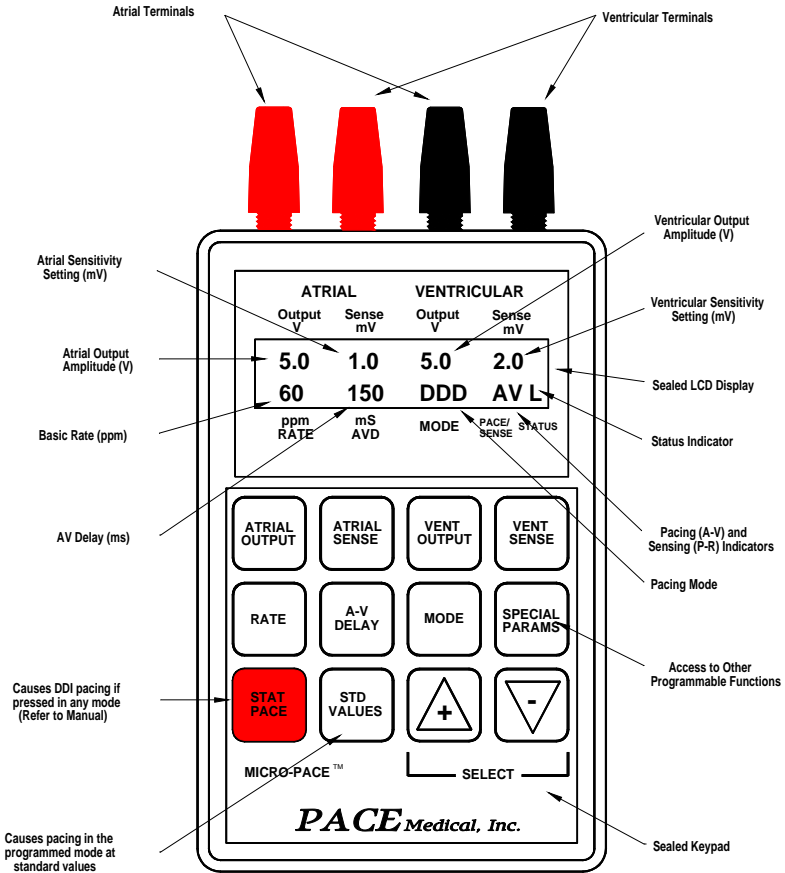


Figure 1

DESCRIPTION OF CONTROL PAD KEYS



Press to activate atrial output amplitude. Change value using + and - arrows. Confirmation is not required.



Press to activate atrial sensitivity. Change value using + and - arrows. Confirmation is not required.



Press to activate ventricular output. Change value using + and - arrows. Confirmation is not required.



Press to activate ventricular sensitivity. Change value using + and - arrows. Confirmation is not required.



Press to activate rate. Change value using + and - arrows. Confirmation is not required.



Press to activate atrioventricular delay. Change value using + and - arrows. Confirmation is not required.



Press to activate mode select. Change mode using + and - arrows. Following selection, press again to confirm.



Press repeatedly to scroll through the less frequently used parameters. Change using + and - arrows. Confirmation is not required.



Press to activate high output pacing in the DDI mode. Confirmation is not required



Press to change all settings of the programmed mode to nominal its 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.

**TABLE 1 - MICRO-PACE 4570 SERIES
SUMMARY OF PARAMETERS AND VALUES**

<u>Parameter</u>	<u>Values</u>	<u>Std/STAT</u>	<u>Steps/Units</u>
Modes	DDD, DDI, DVI, DOO VDD, VVI, VVT, VOO AAI, AAT, AOO	---- / DDI	N/A
Basic Rates ¹	30 - 180	72(60) / 60	1 ppm
Rapid Stimulation ¹	100 - 800	100 / ----	10 ppm
Pulse Amplitude ² (A&V)	0.1 - 2.5 2.5 - 5.0 5.0 - 10.0	5.0 / 10.0	0.1 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)	0.3 - 2.0 1.0 - 3.0	1.0 / 1.0 2.0 / 2.0	0.1 mV 0.1 mV
(Ventricular)	2.0 - 12		Variable
(Atrial)	3.0 - 20		Variable
(Ventricular)			
Atrial Refractory Period ¹			
DDD, DDI, VDD *	196 - 500	250 / 250	AutoPgmd 1.0 ms
AAI	196 - 500	400 / ----	AutoPgmd 1.0 ms
AAT	300 - 500	400 / ----	AutoPgmd 1.0 ms
Ventricular Refractory Period ¹			
DDD, DDI, VDD	196 - 500	325 / 325	AutoPgmd 1.0 ms
DVI, VVI	196 - 500	325 / ----	AutoPgmd 1.0 ms
VVT	300 - 500	325 / ----	AutoPgmd 1.0 ms
AV Delay ¹	50 - 400	150 / 150	AutoPgmd 1.0 ms
Max.Tracking Rate ¹	90 - 230	120 / ----	AutoPgmd 1 ppm
Vent. Blanking Period	10 - 50	30 / 30	1.0 ms
Vent. Safety Pacing	Enabled	Enabled	N/A
PV Delay ¹	25 - 375	125 / ----	AutoPgmd 1.0 ms
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)

GENERAL DESCRIPTION

The Model 4570 MICRO-PACE™ temporary pacemaker is a software programmable, internally-powered stimulator capable of 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 Model 4570 MICRO-PACE incorporates several features not commonly found in other temporary pacemakers. These include: 1) a constant voltage output, 2) a memory function to allow the storage and subsequent retrieval of previously programmed mode parameters, 3) the ability to employ the device as a rapid atrial stimulator from any programmed mode, 4) the limited use of parameter interlocks, low value parameter warnings and time-outs, and visual and audible cueing, all of which are intended to limit inadvertent programming errors, 5) a keypad "lock" to thwart tampering, 6) a means to temporarily suspend output to check on underlying rhythm, 7) a dual-chamber, non-competitive STAT PACE from any mode, 8) an enhanced atrial sensitivity adjustable to 0.3 millivolts, and 9) a "resume operation" function which allows prompt recovery of the last programmed mode and parameter settings after the device has been turned off and back on again.

The case of the Model 4570 MICRO-PACE is fabricated of durable ABS plastic. The sealed keypad is used to access and perform all functions of the pacemaker. The LCD display provides the means for verifying program settings and changes, and for conveniently monitoring operation while in use.

Despite extensive programming capabilities in a Model 4570 MICRO-PACE, it is sufficiently small and light to be worn comfortably by an ambulatory patient. Leg/arm and waist straps made of elastic Velcro® provide for convenient and secure attachment. The MICRO-PACE along with its straps, batteries, and cables is supplied in a sturdy plastic carrying case. When not in use, it is recommended that the MICRO-PACE always be stored in its carrying case to protect it from accidental damage. If a Model 4570 is dropped onto a hard surface, with or without obvious damage, use should be promptly suspended.

Finally, the Model 4570 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 signal filtering. Pacemaker "runaway" is prevented by special rate limiting circuitry.

WARNING: As with any critical medical device, it is of the utmost importance that a Model 4570 and its extension cables be maintained in excellent operating condition. A Model 4570 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.

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.

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

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

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 8 for discussion).

Figure 2.

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 less than 85%

Exceeding the transport and storage temperature range may result in damage to the liquid crystal display (LCD) and keypad of a Model 4570.

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

INDICATIONS, CONTRAINDICATIONS AND WARNINGS

Indications

The Model 4570 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 associated with asystole or bradycardia, symptomatic sinus bradycardia, surgically-induced heart block, and heart block accompanying an acute myocardial infarction.

Additionally, temporary cardiac pacing has been used to overdrive and thereby terminate atrial arrhythmias, including atrial flutter. It has been used in preparation for permanent pacemaker implantation to ascertain the thresholds for sensing and pacing on the acute lead system. Although the intended uses of a Model 4570 MICRO-PACE are primarily therapeutic and prophylactic, the ability to extensively program both the amplitude of the constant voltage output and the pulse width in the MICRO-PACE does make it, when necessary, a satisfactory alternative to a properly functioning Pacing System Analyzer (PSA) for the determination of the thresholds for sensing and stimulation.

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 to 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.

WARNINGS

The Model 4570 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.

Although this Instruction Manual provides reasonable explanations of both operations and functions, it should not be relied upon for a comprehensive understanding of the complexities of cardiac pacing therapy.

The operating instructions contained in this manual should be well understood prior to using a Model 4570 on a patient.

A Model 4570 MICRO-PACE which has been subjected to conditions of transport or storage at temperatures below 10°C (50°F) or above 40°C (104°F), 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.

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.

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.

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.

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.

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.

* In the Model 4570, the maximum triggering rate is limited to the lesser of 60,000 divided by the programmed refractory period, or 200 ppm.

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.

PROGRAMMABLE MODES AND PARAMETERS, CONT'D.

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.

DDI - Improved AV sequential (with intact atrial sensing) pacing

The capability for pacing and sensing is present in both chambers. However, sensed atrial activity will inhibit the atrial output pulse at the end of the V-A interval. DDI is a refinement of the DVI mode and will prevent competitive atrial pacing by maintaining atrial sensing. As with the DVI mode, AV sequential pacing at the programmed rate will be provided in the absence of intrinsic activity. Additionally, intrinsic ventricular activity occurring during the atrial escape interval or AV delay will inhibit the pacemaker and reset the timing as previously described. However, unlike the DVI mode, intrinsic atrial activity during the atrial alert period will inhibit the atrial output pulse and prevent competitive atrial pacing. This sensing will not affect pacemaker timing and, in the absence of intrinsic ventricular activity, a ventricular output pulse will be provided at the basic rate. As with the DVI mode, a ventricular blanking period occurs coincident with any atrial output pulse.

VDD - Atrial tracking, ventricular inhibited pacing

This mode allows for sensing in both chambers, but pacing only in the ventricle. In the absence of intrinsic activity, the ventricle will be paced at the programmed rate. Intrinsic atrial activity during the atrial alert period will 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 sensing interval. Atrial activity may be only be detected and tracked from the end of the PVARP up to the end of the atrial escape interval. Thus, there is no difference between the programmed rate and the minimum tracked rate.

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, CONT'D.

Basic Pacing Rate

The Model 4570 may be programmed from 30 ppm to 180 ppm in increments of 1 ppm in any single-chamber or dual-chamber pacing mode. All ventricular modes have a standard rate of 72 ppm. All other modes have a standard rate of 60 ppm. Rates below 45 ppm are intended for temporary diagnostic purposes. If the operator attempts 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 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 Model 4570 MICRO-PACE is rate limited to 240 ppm on the ventricular channel in all modes, except the Rapid Atrial Stimulating mode.

Pulse Amplitude

The pulse amplitude of the Model 4570 MICRO-PACE is programmable in steps of 0.1V from 0.1 to 2.5V, in steps of 0.5V from 2.5 to 5.0V, and in steps of 1.0V from 5 to 10V. If the operator attempts 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 low battery indicator, "L", on the status display.

Pulse Width

Pulse width for the Model 4570 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 the operator attempts to reduce pulse width below this level. At the end of 60 seconds, pulse width will revert to the standard 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 low battery indicator, "L", on the status display.

Sensitivity

Atrial sensitivity may be programmed from 0.3 to 12 millivolts. From 0.3 to 2.0 millivolts, the steps are 0.1 millivolt. From 2.0 to 4.0 millivolts, the steps are 0.2 millivolt. From 4.0 to 6.0 millivolts, the steps are 0.5 millivolt. Between 6.0 and 8.0 millivolts the increment is 1.0 millivolts. And, from 8.0 to 12 millivolts, the increment is 2.0 millivolts. Ventricular sensitivity may be programmed from 1.0 to 20 millivolts. From 1.0 to 3.0 millivolts, the steps are 0.1 millivolt. From 3.0 to 5.0 millivolts, the steps are 0.2 millivolt. From 5.0 to 8.0 millivolts, the steps are 0.5 millivolt. And, from 8.0 to 20 millivolts, the increment is 4.0 millivolts. The lower the numerical value, the higher the sensitivity. If the operator attempts to program a value greater than 5mV, the brief warning message, "Leaving Typical Sensing Range", will be displayed.

PROGRAMMABLE MODES AND PARAMETERS, CONT'D.

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 2 - 4 fold margin of safety. Unless the value so determined is smaller than that available with the standard values, it is recommended that standard values be used. The standard values are generally adequate in the acute setting.

It is recommended that physicians avoid making unnecessary changes in the standard settings 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.

NOTE: Use of short pacing intervals (high pacing rates) with long refractory periods may result in intermittent asynchronous pacing and may be contraindicated in some patients. Additionally, when programmed to high output levels, the standard refractory period on the ventricular channel may be inadequate to prevent detection of "noise" associated with the ventricular output pulse, resulting in a recycling of the noise sampling period. When this is occurring, a dot will be seen alternating with the "V" enunciator. Extending the refractory period just enough to eliminate the dot is recommended.

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.

PROGRAMMABLE MODES AND PARAMETERS, CONT'D.

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 17 for automatic changes with increasing rate in dual-chamber modes.

AV Delay

The AV delay defines the time interval between an atrial output pulse and a ventricular output pulse. The available range of AV delays 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 standard value for AV delay is 150 milliseconds. See page 17 for automatic changes with increasing rate in dual-chamber modes.

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 Special Parameters loop 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).

PROGRAMMABLE MODES AND PARAMETERS, CONT'D.

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. The operator must 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.

Blanking Period / Crosstalk

When a Model 4570 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 standard value is 30 milliseconds. Blanking periods are an inherently undesirable, but necessary parameter in dual unipolar pacing modes which have traditionally employed a common indifferent. However, they also find utility in dual bipolar configurations where complete isolation of the atrial and ventricular channels, particularly over the very broad ranges of output and sensitivity available in some devices, is impractical or impossible.

Thus, this brief period of refractoriness 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 condition is commonly called "crosstalk". Namely, the proper function of one channel causes proper, but inappropriate function in the other. 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.

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 standard 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 produce 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.

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 Model 4570, 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".

Inhibit Output

To inhibit the output of the Model 4570 MICRO-PACE, ex. to evaluate a patient's underlying rhythm, press the SPECIAL PARAMS 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 Special Parameters display and return of the normal status display. This sequence is shown by Figures 3 and 4, below.



Figure 3.

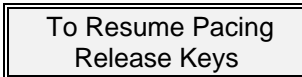


Figure 4.

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.

ADDITIONAL FEATURES/OPTIONS, CONT'D.

PMT Termination Algorithm

The Model 4570 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 P wave. Such events are usually 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 Model 4570 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.

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 two ventricular events with no intervening 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 is commonly called "DVI on PVC".

Resume Operation

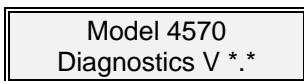
The Model 4570 is equipped with the ability to be turned off and then on again, promptly recovering the previously operating mode and parameter settings. This is accomplished by moving the OFF/ON/LOCK switch to ON followed immediately by a single press of the SELECT Down [-] key. Although a display will appear briefly to prompt this action, the recovery of the mode and parameters can be speeded by pressing the key any time immediately following switch activation. Also, during this time, the [-] key will function even if the OFF/ON/LOCK switch has been inadvertently moved beyond ON to LOCK. Pressing any other parameter or the mode key will promptly produce the status display and pressing the STAT PACE key will instantly activate emergency pacing.

PACEMAKER OPERATIONS

Power Off/On/Lock

The OFF/ON/LOCK switch is located on the upper left-hand side of the MICRO-PACE. This recessed switch is designed to move smoothly from OFF to ON, and to the LOCK position when it is the operator's intention to render the keypad inoperative. The recessed design of the switch facilitates rapid activation, but substantially limits the risk of inadvertent switch position changes. To turn the unit off, depress the switch guard latch and move the switch to OFF.

When first turned ON following battery insertion, the MICRO-PACE will briefly display the phrase, "Model 4570 Diagnostics V*.*", to indicate that an automatic electronic check is being made on the integrity of vital operational components as shown in Figure 5. During any subsequent power on, the display in Figure 5 is replaced by, "Pacing DDD Mode - Std Values", as shown in Figure 6. That is quickly followed by, "[–] Resumes Last Mode (XXX)", where "XXX" is the previously programmed mode, as shown in Figure 7. This allows the user to select the standard power on mode of DDD at standard settings or the previously programmed mode and parameter settings. The display instructs the user to press the SELECT Down [–] key, if immediate return to the previously operating mode is desired. Pressing this key while turning the device on will speed the process. If the battery is low at power on, this display will also include an "L" in the extreme right-hand enunciator position. Finally, the main status display is presented showing the primary pacing parameters and values (Figure 8).



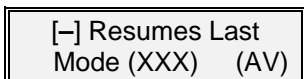
Model 4570
Diagnostics V*.*

Figure 5.



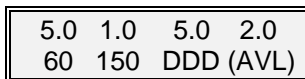
Pacing DDD Mode
Std Values (AV)

Figure 6.



[–] Resumes Last
Mode (XXX) (AV)

Figure 7.



5.0 1.0 5.0 2.0
60 150 DDD (AVL)

Figure 8.

↖ Blinks A or V with each paced beat; blinks P or R on each sensed beat; and shows L with low battery

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.

PACEMAKER OPERATIONS, CONT'D.

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. Also, it is important to note that crosstalk may 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 evoking 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

Normal Bipolar Configuration

The output terminals of the Model 4570 MICRO-PACE are capable of accepting and holding standard pacing lead pin connectors as well as typical surgical heartwires securely. Each output consists of a pair of terminals; one black and one red. The pair closest to the LCD display of the MICRO-PACE is ventricular and the pair closest to the back is atrial. Each pair is also labeled as to its function and the polarity of the individual terminals. With the MICRO-PACE OFF, connect the pacing leads to the appropriate terminals. Observe polarity. Tighten terminals securely, **but not more than finger tight**; do not apply a tool of any kind. Changes in the settings or the mode may be made, following the instructions which begin on page 15.

Modified Bipolar Configuration

This configuration should be used with caution. To adapt an indwelling bipolar lead system which has suffered 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 A and V outputs 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.

Standard Pacing

Pressing the STD VALUES key will immediately return all operational parameters of a Model 4570 MICRO-PACE to their nominal or standard values in the mode then programmed. The confirmation message, "NOTE: Values Set To Standard", appears briefly in the display.

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 mode previously programmed. When [STAT PACE] is pressed, there is a brief message, "WARNING: Enabling Emergency DDI". Return of the status display accompanied by an audible beep confirms completion of the command.

This 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.

PACEMAKER OPERATIONS, CONT'D.

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 this latter problem. Selection of an asynchronous pacing mode (pref. 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.

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. This is accomplished by pressing either the SELECT Up or the SELECT 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.

Current Mode: DDD
[MODE] Re-enters

After 1st press of MODE

Select Mode: VVI
[MODE] Confirms

After using up [+] and / or [-]

CONFIRMED
Mode is now VVI

Confirming display following
2nd press of [MODE]

OFF	OFF	5.0	2.0
60	OFF	VVI	(V)

New status display

Figure 9

PROGRAMMING, CONT'D.

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 change within sixty seconds of a key press or the pressing of any key other than MODE or SELECT Up or Down 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.

NO CONFIRMATION: Mode Not Changed

Figure 10.

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 SELECT Up or Down key to adjust the selected parameter value. The new value left in the status display will take effect immediately. No further action from the operator is required. The cursor will disappear sixty (60) seconds following the last key press. If more than one parameter value change is being made, the operator may proceed from one parameter to another without waiting for the disappearance of the cursor. The basic process just described is shown pictorially in Figure 11 for a change in rate.

5.0	1.0	5.0	2.0
60	150	DDD	(AV)

Initial status display in DDD
at standard settings

5.0	1.0	5.0	2.0
<u>60</u>	150	DDD	(AV)

Display after [RATE] key is
pressed / cursor under rate (60).

5.0	1.0	5.0	2.0
70	150	DDD	(AV)

Display after use of [+] / [-] to
change rate - cursor will disappear

Figure 11.

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.

PROGRAMMING, CONT'D.

If the operator attempts 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 of the status display parameters require very specific operator action to access values that are generally clinically inappropriate or useful for test purposes only. In the case of pulse amplitude, the operator must press the ATRIAL OUTPUT or VENT OUTPUT key when prompted by the status display in order to program abnormally low values. This serves as a warning to the operator that he/she is entering a range of values 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.

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 standard value. Changes are made known to the operator both by display messages and by audible beeps.

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.

NOTE: As an aid to programming, the parameters rate, pulse amplitude, pulse width, and sensitivity will not change with changes in mode.

Automatic Programming of Dual-Chamber Parameters for High Rates

To facilitate the programming of high dual-chamber pacing rates without the requirement for the operator to adjust conflicting parameters such as AV delay and refractory periods, the Model 4570 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 will be 196 milliseconds and the maximum AV delay will be 87 milliseconds with the rate at 180 ppm (150 ms in DOO). 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.

PROGRAMMING, CONT'D.

Special Parameters

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

To change the value of a Special Parameter, press the SPECIAL PARAMS key until the desired parameter is displayed along with its present value, highlighted with a cursor. The SELECT Up or Down key is generally used to scroll through the options to the value desired. In some instances, the SELECT Up or Down key is used to enable or disable a function. The value or function above the cursor is automatically programmed and no further action by the operator is required. After sixty seconds, the status display returns accompanied by an audible beep. This sequence is depicted in Figure 13.

5.0	1.0	5.0	2.0
60	150	DDD	(AV)

Initial Display

Memorize: [+] key
Recall: [-] key

Display after pressing
[SPECIAL PARAMS]

PVARP = 250 mS
(Block >160 PPM)

Display after additional
presses of [SPECIAL PARAMS]

PVARP = 235 mS
(Block >166 PPM)

Display after using [+] / [-]
to obtain new value.

Figure 13.

NOTE: Of the programmable parameters, only pulse width has the automatic low value reversion feature which is described on pages 7 and 17.

PROGRAMMING, CONT'D.

Rapid Atrial Stimulation

Rapid atrial stimulation mode is a Special Parameter which is accessed by pressing the SPECIAL PARAMS key. Once the rapid stimulating mode is displayed, "Rapid = 100PPM / (Pacing = XXXPPM)", the rate may be varied from a low of 100 ppm to a maximum of 800 ppm by using the SELECT Up or Down keys. 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 SELECT Up or Down keys while pressing and holding the RATE key. Figure 14, below, describes the process of accessing and activating the Rapid Atrial Stimulation mode.

OFF	OFF	5.0	2.0
72	OFF	VVI	(V)

Beginning point is any mode

Rapid = 100 PPM (Pacing = 72 PPM)

Press [SPECIAL PARAMS]
until above display appears

Rapid = 500 PPM (Pacing = 72 PPM)

Use [+] / [-] to obtain
rate desired

WARNING: Pacing Rate = 500 PPM

Constant display when [RATE]
is held down, activating
rapid stimulation.

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.

MEMORY

To facilitate system testing and to speed the reprogramming process that may necessarily result, the Model 4570 MICRO-PACE allows an operator to enter previously programmed parameter values to memory and thereafter recall them at will. Note, however, that only one set of RECALL parameters may be memorized per mode.

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

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

To maintain preselected pacing parameters during a battery change, replace batteries one at a time, if two batteries are in use, or insert a new one before removing the old one, if only one battery is being used. As long as one battery in the device, at any given time, remains good, memorized / preselected values will be retained and pacing will continue.

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. The Model 4570 pacemaker has been designed to maintain a constant surveillance of critical components and operations and, in the event an abnormality or failure is detected, to provide an alert to the operator and, in some instances, to automatically adjust the pacemaker 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 standard 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 to alert the operator to 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 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 5.0 V 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 DVI 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).

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. Turn the device ON.
2. With mode set to VVI and output set to minimum, set sensitivity to any value which produces consistent sensing.
3. Reduce the rate to 10 ppm below the patient's intrinsic rate.
4. Slowly decrease sensitivity (increase setting value) until sensing is lost and a pacemaker output pulse is delivered.
5. 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 Model 4570 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) radiation. 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 Model 4570 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 Model 4570 MICRO-PACE may be seriously damaged by the inappropriate proximate application of electrocautery / electrosurgical devices, whether to the device or to the leads connected to the device.

If a procedure involving the use of EC / ES equipment is planned on a patient wearing a MICRO-PACE, it is 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.

A Model 4570 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.

EXTENSION CABLES

Each Model 4570 is supplied with two extension cables which permit the user to locate the pacemaker up to eight feet away from a patient. One of the cables is labeled "Atrium"; the other cable is labeled "Ventricle". This aids the identification of the cables during dual-chamber pacing procedures. The proximal end of the cable is a molded fixed pin connector with protected boots that fit directly into the output terminals. The connector terminals on the distal end are equivalent to those on the Model 4570 and are capable of securely grasping any pacing lead from the diameter of a heartwire to a 2mm implantable lead connector pin.

Instructions for Use

With the Model 4570 off, connect the cables by unscrewing the terminal caps of the device completely and inserting the connector pins of each extension cable into the terminals until fully seated. Observe polarity and ensure that the appropriate (atrial or ventricular) cable is in each terminal pair. Tighten terminals finger-tight only. **Do Not Over-Tighten.** Do not use tools. At the distal end, unscrew the terminal caps of the extension cables completely and insert the appropriate lead or heartwire. Observe polarity. Tighten each terminal as above.

WARNING: When using extension cables with the Model 4570, 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.

Re-sterilization of Extension Cables

Following use, the Model 4570 extension cables may be cleaned with 70% isopropyl alcohol. Air dry. Sterilize by autoclaving at 121° C for 30 minutes. **Do not attempt to resterilize extension cables using EtO or gamma irradiation.** Either of these processes may damage the cables, necessitating premature replacement.

NORMAL MAINTENANCE

As previously described, a Model 4570 MICRO-PACE is both durable and water resistant. It is not water-proof. If cleaning is required, it is recommended that a cloth or sponge simply dampened with warm water and a small amount of non-abrasive detergent or disinfectant solution, NOT WET, be used to wipe the device. No unusual maintenance is otherwise required.

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. The Velcro elastic straps may be machine washed with laundry detergent. The wear life of each strap will be extended, if the entire "hook" portion of the strap is connected to the strap body, as would be the case while in use. This will prevent accumulation of lint in the "hook" portion and reduce its tendency to catch on other materials.

WARNING: Do not sterilize a MICRO-PACE by use of autoclaving (EtO or steam), ultrasonics or gamma irradiation. Do not immerse in cleaning or sterilizing solutions. Such procedures can seriously damage a MICRO-PACE.

LOW BATTERY INDICATOR AND BATTERY REPLACEMENT

The Model 4570 MICRO-PACE is designed so that it may be operated on one or two 9 volt alkaline (IEC Type 6LR61) or lithium batteries. It is recommended that fresh batteries be installed prior to each use.

USE ONLY FRESH 9 VOLT ALKALINE (OR LITHIUM) BATTERIES

A typical MICRO-PACE pacemaker will operate at standard DDD settings for about one week with two Duracell Model MN1604 or ENERGIZER Model 522 alkaline batteries installed, and for about two and one half weeks with two Model U9VL ULTRALIFE lithium batteries installed. Single battery operating time is about half of these respective times.

Low battery condition will be indicated by an "L" in the lower right-hand corner of the status display, and a tone and the message, "WARNING: Replace 9 Volt Battery", which occurs every 4.25 minutes. With two alkaline batteries installed the low battery warning period is about 24 hours. Should a low battery indication occur during use, it is recommended that the Model 4570 be temporarily replaced with another unit while the batteries are changed.

To maintain preselected pacing parameters during the battery change, replace the batteries one at a time, if two batteries are in use, or insert a new one before removing the old one, if only one battery is being used. As long as one battery in the device, at any given time, remains good, memorized / preselected values will be retained during a battery change.

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.

WARNING: 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 or Mercury biomedical batteries in a Model 4570.

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, as is becoming more common, 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 Model 4570, if it has been dropped onto a hard surface. Regardless of an apparent absence of damage, hidden damage may have been sustained which may cause device malfunction. Factory service is recommended. See Service, below.

STORAGE

The carrying case of the Model 4570 affords considerable protection from accidental damage both while in transit and in storage. Try to select a storage location that is cool (about 20° C or 68° F) and dry. In no event should a Model 4570 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 LCD display may result.

DO NOT store a Model 4570 for any extended period, with the batteries in place. Battery leakage may cause corrosion of the battery terminals and damage the device's electronics.

SERVICE

In the event your Model 4570 MICRO-PACE should fail 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., Welwyn Garden City, England for repair. Please enclose a letter or report detailing the problem encountered. If available, 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 the company at (781) 890-5656 (Pace Medical, Inc.) or (0707) 327641 (APC Medical Ltd.) 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.

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INTERNATIONAL CLASSIFICATIONS AND CERTIFICATIONS

The Model 4570 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

The Model 4570 is classified as a Type CF defibrillation-proof applied part and bears the international symbol identifying it as such shown below:



The Model 4570 bears the CE Mark to indicate its compliance with the requirements of Annex I of Council Directive 93/42/EEC, known as the "Medical Device Directive".



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 less than 85%

Exceeding the transport and storage temperature range may result in damage to the liquid crystal display (LCD) and keypad of a Model 4570.