

**This manual describes the operation
of an AccuPace™ Pacing Analyzer,
Models 4800, 4801 and 4802
with software version 2.0. The software version
number is identified on the LCD display
at first power on following battery insertion.**

INSTRUCTION MANUAL

**AccuPace™
REF 4800
Dual-Chamber
Pacing Analyzer**

Models 4800, 4801 and 4802

**Pace Medical, Inc.
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Waltham, MA 02451**

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

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SPECIFICATIONS

PACING PARAMETERS AND VALUES

<u>Parameter</u>	<u>Values</u>	<u>Nominal/STAT</u>	<u>Steps/Units</u>
Modes:	Demand: DDD, DDI, DVI, VVI and AAI	---/DDI	N/A
	Asynchronous: DOO, VOO, AOO		
Basic Rates ¹	(Atrial) 30 - 180ppm (Ventricular) 30 - 180ppm (Dual) 30 - 180ppm	70/--- 70/--- 60/60	1 ppm 1 ppm 1 ppm
Rapid Stimulation ¹	60 - 990ppm	100/---	10 ppm
Pulse Amplitude ² (A&V)	0.1 - 10.0V	3.5/10.0	0.1V
Pulse Width ³³ (A&V)	0.05 - 1.0ms 1.0 - 2.0ms	0.40/1.5	0.05ms 0.1ms
Sensitivity ⁴ (Atrial) (Ventricular)	0.5 - 10.0mV 1.0 - 10.0mV 10.0 - 20.0mV	1.0/1.0 2.0/2.0	0.5mV 0.5mV 1.0mV
Refractory Period ¹ (Nominal) (Dual Chamber/High Rates)	250 or 330ms 200 - 330ms	250/250	Auto Pgmd Auto Pgmd
AV Delay ¹	15 - 300ms	150/150	1.0ms
PV Delay ¹	*AV delay minus 25ms	125/---	Auto Pgmd
Maximum Tracking Rate ¹	40ppm > Rate	100/---	Auto Pgmd
Ventr. Blanking Period ¹	30ms	30/30	Fixed
Ventricular Safety Pacing ¹	120ms	Enabled	Fixed
PMT Limit ¹	40bpm > Rate	100/---	Auto Pgmd
PMT Term. Algorithm	10 Beats > PMTR	10/---	Fixed
PVC Response	1 cycle DVI	Enabled/---	Fixed

*Gradually reduces below 50ms AV delay to a minimum of 15 ms.
Refer to discussion on page 11.

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

¹ = ± 1 - 5%

² = ±10%

³ = the greater of
± 10% or 0.05V

⁴ = ± 20%

TEST SPECIFICATIONS

<u>Patient/Lead System Tests</u>	<u>Range</u>	<u>Increment</u>
* Stimulation Impedances ¹ w/ Outputs < 1.0 Volts and/or PW < 0.10ms	50 - 2000 Ohms	1 Ohm
* Stimulation Impedances ¹ w/ Outputs > 1.0 Volts and PW >= 0.10ms	50 - 4000 Ohms	1 Ohm
P Wave Amplitude ²	0.5 - 9.99mV 10.0 - 20.0mV	0.01mV 0.1mV
R Wave Amplitude ²	1.0 - 9.99mV 10.0 - 20.0mV	0.01mV 0.1mV
** Capture Thresholds		
Pulse Amplitude *	0.10 - 10.0V	0.1V
Pulse Width *	0.05 - 0.95ms 1.0 - 2.0ms	0.05ms 0.1ms
Retrograde Conduction ³	180 - 600ms	1.0ms
Slew Rates ²²	0.05 - 5.00V/S	0.01V/S
Resultant Current - (atrial or ventricular)	0.1 - >100.0mA	0.1/1.0mA

Accuracy: ¹ = > 0.1 ms ± 20% ² = ± 15% ²² = ± 20% ³ = ± 5% ³³ = ± 10%
< 0.1 ms ± 30%

*Current programmed values are recorded into memory as the Capture Thresholds when the STORE CAPTURE key is pressed.

CAUTION: Variations in test methodology exist between manufacturers of implantable pacing systems as well as analyzers. It is recommended that the user of an AccuPace maintain a record of the values measured by both devices at implant, initially, so that an assessment of repeatability and acceptability may be made.

* Stimulation impedances are reported at the programmed pulse amplitude and pulse width.

**Capture thresholds are performed and reported at user selected pulse amplitude and pulse width.

Note: Nominal factory rate settings when turned on are 70 ppm for single chamber modes and 60 ppm for dual chamber modes. When initially energized rate settings are 30 ppm, or if using the RESUME ON key, the device will operate in the last operating condition.

KEY TO ANALYZER CONTROLS

Pacing Parameter Controls:

CHANGE VALUE Changes the value of the selected parameter; selected parameter is indicated on the display by the cursor.

RATE

Selects Rate parameter for change.

A-V
DELAY

Selects AV Delay parameter for change; dual-chamber modes only.

OUTPUT
AMPL

Selects Output Amplitude parameter for change; selects A or V output depending on the lead currently displayed.

PULSE
WIDTH

Selects Pulse Width parameter for change; selects A or V pulse width depending on the lead currently displayed.

SENSE

Selects Sensitivity parameter for change; selects A or V sensitivity depending on the lead currently displayed.

Pacing Mode Controls:

ASYNCH
DEMAND

Changes pacing mode between asynchronous and demand (inhibited) operation:

<u>Demand</u>	<u>Asynch</u>
AAI	AOO
VVI	VOO
DVI	DOO
DDD	DOO
DDI	DOO

AAI
ON

Turns unit on in AAI (atrial inhibited) mode at nominal settings, except rate, which will be 30 ppm. If unit is on, changes mode to AAI at current settings.

VVI
ON

Turns unit on in VVI (ventricular inhibited) mode at nominal settings, except rate, which will be 30 ppm. If unit is on, changes mode to VVI at current settings.

DVI
ON

Turns unit on in DVI (AV sequential inhibited) mode at nominal settings, except rate which will be 300ppm. If unit is on, changes mode to DVI at current settings.

DDD
ON

Turns unit on in DDD (AV universal) mode at nominal settings, except rate which will be 30 ppm. If unit is on, changes mode to DDD at current settings.

STAT
(DDI)

Turns unit on in DDI (atrial and ventricular inhibited) mode at maximum output. If unit is on, changes mode to DDI at maximum output. Emergency mode to re-establish capture, if possible, without repositioning lead.

KEY TO ANALYZER CONTROLS, Continued

Special Pacing Controls:

MAX
OUTPUT

Temporarily changes pacing output to maximum (10V @ 2ms) on lead currently displayed, as long as key is held.

INHIBIT
A-OUT

Turns off atrial output if present in current pacing mode. Pressing this key again will restore atrial output.

INHIBIT
V-OUT

Turns off ventricular output if present in current pacing mode. Pressing this key again will restore ventricular output.

RAPID
ATRIAL

Selects Rapid Atrial Rate parameter for change. Enables the Pace Rapid key.

PACE
RAPID

Initiates rapid atrial pacing as long as key is held. The Rapid Atrial key must be pressed first to enable Pace Rapid.

NOMINAL

Immediately changes all pacing parameters in the current mode to nominal settings.

RESUME
ON

Turns unit on in the same pacing mode, same settings, and the same patient data as when it was last turned off.

Lead Test Controls:

LEAD

MEASURE

Press and hold to measure impedance and current for lead currently displayed. Updates measurement on each pacing output. Release to save last measurement taken.

RETRO (VDI)

MEASURE

Press and hold to test for retrograde conduction; unit will change to VDI mode (VVI with atrial sensing) at a rate of 100 ppm or programmed rate if greater. Hold key until test results appear on the display. Normal operation will resume when test ends or the key is released.

CAPTURE

STORE

Press to store the currently displayed output settings as the capture threshold. Amplitude and pulse width settings will be saved on display and in memory. Pacing output for the lead under test will return to nominal settings.

P / R WAVE

MEASURE

Press and hold to measure amplitude and slew rate of the sensed signal on the lead currently displayed. Temporarily changes sensitivity to maximum. Updates measurement on each sensed event. Release to save last measurement taken.

KEY TO ANALYZER CONTROLS, Continued

System Controls:

ATRIAL
VENTR

Selects which lead parameters are to be displayed. A legend appears on the display to denote the selected lead. Output amplitude, pulse width, sensitivity, and all measured lead parameters are displayed for the selected lead.

MENU

Selects and deselects menu mode. In menu mode, special functions menu appears on the bottom line of the display. Change value wheel scrolls through available functions (refer to other sections of this manual).

CONFIRM

In menu mode, accepts currently displayed option and advances the function to the next level (refer to other sections of this manual).

PRINT
DATA

Initiates the Print Data sequence to download data to remote printer. Allows selection of current or archive data.

CLEAR
DATA

Clears out any current lead data (both leads) and patient ID data is not lost, but is moved to archive and may still be printed.

OFF

Turns unit off and saves all pacing settings, patient ID, and lead data. Data will not be lost thereafter, even if batteries are removed.

INTERNATIONAL CLASSIFICATION AND CERTIFICATIONS

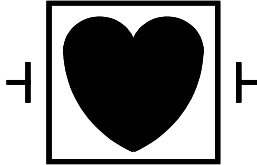
The AccuPace Pacing Analyzer has been tested to ensure compliance with the intent of Directive 89/336/EEC for Electromagnetic Compatibility.

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



The AccuPace 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".



GENERAL DESCRIPTION

The AccuPace Pacing Analyzer is an internally powered, software-programmable device designed for continuous operation in the acute cardiac-care environment as both a temporary cardiac pacemaker and a Pacing Analyzer. Extensive multi-parameter, multi-mode programmability is particularly desirable during the primary implantation of a permanent pulse generator where the ability to mimic the implantable device as closely as possible can have great short-term and long-term significance.

The AccuPace Pacing Analyzer is a constant voltage output device, capable of operating in all of the commonly utilized pacing modes from ventricular or atrial asynchronous (VOO or AOO) to AV Universal (DDD) pacing. In addition, those pacing parameters that may need to be adjusted to suit the specific needs of a patient, may be varied over a broad range, yet in increments, fine or coarse, which are more physiologically or diagnostically appropriate to that portion of the range of values. Programmable parameters include: rate, sensitivity, pulse amplitude, pulse width, and AV delay. Additional non-programmable parameters of interest include: maximum tracking rate which varies with rate, blanking period, ventricular safety pacing, PVC response, and a pacemaker-mediated tachycardia (PMT) termination algorithm.

Also, the AccuPace Pacing Analyzer incorporates several additional features to simplify and broaden application. These include, among others: 1) a memory function to allow the storage and subsequent retrieval and printing of previously programmed data and measured information via an infrared (IR) link, 2) instant ON in any desired inhibited mode, 3) immediate output inhibition and recovery with the press of a key, 4) continuous display of pacing status and test data, 5) a backlit liquid crystal display (LCD), 6) non-volatile memory, and 7) a temporary maximum output key.

The display of the AccuPace is configured to provide the user with all the information that may be required to perform the operations necessary to use the device either as a stimulator or a Pacing Analyzer. Legends, mode, parameter values, and test results are all displayed in a clear and concise manner. The AccuPace keypad and display format are shown in Figure 1. The case of the device is fabricated of durable ABS plastic. A sealed keypad and a Control Wheel are used to access and perform all functions of the analyzer, largely eliminating the potential for failure of mechanical switches. Additionally, the keypad provides a higher degree of resistance to fluid intrusion than is customarily found in conventional electronic devices.

The AccuPace, along with batteries and cables (Pace Line cables are provided with the Models 4800 and 4802 only), is supplied in a rugged, soft pack carrying case. When not in use, it is recommended that the AccuPace always be stored in its carrying case to protect it from accidental damage with batteries removed.

Finally, the AccuPace is fully electrically isolated. The circuit is protected from 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.

WARNING: As with any critical medical device, it is of the utmost importance that an AccuPace be maintained in excellent operating condition. Any device that 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 retesting. Serious adverse effects may be associated with the use of an impaired medical device.

Damaged extension cables should be promptly replaced.

ACCESSORY CABLES - CONNECTION AND CARE

The Model 4800 is supplied with two Pace Line™ extension cables, Model 4280 Series. The series of Pace Line autoclavable cables has a molded fixed pin connector with protected boots at the proximal end (device end) that fit directly into the output terminals of the device.

For Model 4801, please refer to the cable manufacturer's guide for connecting the cables to the adapter. The adapter and cables are not supplied by Pace Medical or APC Medical. The AccuPace 4801, is designed to accept a unique 6 pin male Redel® connector adapter which connects directly to the single 6 pin female Redel output connector on the AccuPace. The Atrial and Ventricular channels are marked on the distal end of the adapter for connection to patient cables.

The Model 4802 is supplied with two Pace Line extension cables, Model 5280 Series. This series of Pace Line autoclavable cables have a unique 2 pin male Redel connector at the proximal end (device end) that fit directly into the output terminals of the device.

Attention: For Pace Line cables only. One of the cables is labeled "Atrium", the other cable is labeled "Ventricle". This aids in the identification of the cables during dual-chamber procedures. The proximal end of each cable has a molded fixed pin connector or a unique 2 pin male Redel connector which will fit directly into the output connector of the AccuPace. The insulated alligator clips on the distal end provide a secure means of attachment to the temporary or permanent pacing leads.

Instructions for Use

With the Model 4800 off, connect the cables by unscrewing the terminal caps 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 terminal caps finger-tight only. **Do Not Over-Tighten.** At the distal end, the terminating alligator clips are also labeled as to channel and polarity.

With the Model 4801 off, connect adapter by inserting the unique 6 pin Redel connector of the adapter into the terminal on top of the AccuPace until fully seated. Attach Atrial and Ventricular patient cables to the adapter. Ensure that the appropriate (atrial or ventricular) cable is in the properly labeled position on the adapter terminal.

With the Model 4802 off, connect the Pace Line cables by inserting the unique 2 pin Redel connector, of each extension cable into the terminals until fully seated. Ensure that the appropriate (atrial or ventricular) cable is in each terminal. At the distal end the terminating alligator clips are also labeled as to channel and polarity.

Sterilization

Before use, the Pace Line cables may be cleaned with mild detergent and water, rinsed and sterilized by autoclaving using a standard U.S. Pharmacopoeia cycle of 15 minutes at a temperature of 121°C or the British Pharmacopoeia cycle of 30 minutes at 115°C.

CAUTION: Extension cables which are repeatedly autoclaved should be periodically examined to ensure that there is no diminishment of the integrity of the cable with respect to its outer insulation and the resistance of the conductors (< 2 ohms). A cable showing any signs of physical deterioration should be promptly replaced.

KEY TO STATUS INDICATORS

A = Issuance of Atrial Output Pulse	V = Issuance of Ventricular Output Pulse
P = Atrial Channel Sensing Event	R = Ventricular Channel Sensing Event
N = Electromagnetic Interference (EMI)	S = Device is Performing Ventricular Safety Pacing
W = Electronic Wenckebach is Being Performed in the Presence of a High Atrial Rate	B = 2:1 or Higher AV Block is Being Performed in the Presence of a High Atrial Rate
• = Signal Detected in the Refractory Alert Period; See Discussion on Page 8.	L = Low Batteries; Prompt Replacement Recommended.

Figure 2.

INDICATIONS, CONTRAINDICATIONS, WARNINGS AND POTENTIAL COMPLICATIONS

NOTE: If an AccuPace has been exposed to very warm or very cold temperatures during transport, it should be allowed to come to room temperature prior to use.

Indications

The AccuPace Pacing Analyzer is intended for use in the following circumstances:

1. To provide multi-modal and multi-parameter stimulation capability during Implant or revision of a permanent cardiac pacing system.
2. To provide a means for assessing the characteristics of implanted lead systems.
3. To provide a means for the printing out of data, including measured data, stored in memory.
4. To provide a means for delivering rapid atrial stimulation should it be needed during the course of implant or permanent pacing system revision.
5. To provide a means for assessing whether retrograde (VA) conduction is present in a patient and a measurement of the VP interval.

Contraindications

There are no known contraindications to the use of a normally functioning pacing analyzer when properly applied for the indications listed above.

Warnings: A patient should be continuously monitored and attended while a pacing analyzer is pacing a patient. Cardiac pacing leads or heart wires provide a direct electrical pathway to the heart. Strict attention to electrical safety practices must always be observed when performing cardiac pacing procedures 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.

The means for prompt resuscitation of a patient should always be close at hand.

This Pacing Analyzer is intended for use with bipolar lead systems. Use with unipolar configurations may require the use of independent indifferents. See "Connection to Pacing Leads", page 19. The AccuPace Pacing Analyzer is a sophisticated electronic instrument, designed and manufactured to the highest standards. Nevertheless, as is typical of any such device, random component failure, damage due to mishandling, and battery depletion may limit its ability to perform in accord with its specifications. See also Potential Complications, below, and the warning on page 1.

INDICATIONS, CONTRAINDICATIONS, WARNINGS AND POTENTIAL COMPLICATIONS, Continued

Warnings, Continued: The AccuPace Pacing Analyzer must NOT be subjected to sterilization processes: EtO, gamma, or steam. The AccuPace is NOT designed to be immersed in cleaning or disinfecting solutions.

Environmental electromagnetic interference, particularly that due to the proximate use of electrocautery / electrocoagulation devices, is known to interfere with the operation of pulse generators operating in a sensing mode. If the AccuPace detects electromagnetic interference, one or more of the following responses may be seen: output inhibition, interference rate operation, and / or tracking operation, if the AccuPace is programmed to DDD mode. Refer to page 24 for further discussion.

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.

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.

Potential Complications

The AccuPace Pacing Analyzer, in good operating condition, and used in accord with its instructions, will provide effective service as a means of evaluating important pacing parameters at the time of primary implant of a permanent pacing system or at subsequent revision, while at the same time providing pacing support to the patient as may be required. Nevertheless, certain environmental influences, ex. detected EMI, random component failure, and malfunctions associated with misuse or inadvertent damage to any device intended for use in maintaining an adequate, regular heart rhythm, may produce a limited number of potential complications. Among these are:

1. Failure to provide adequate support for the patient due to the loss of a properly timed output pulse and attendant bradycardia or asystole.
2. Failure of proper detection of the patient's intrinsic depolarization signal, resulting in pacemaker competition and arrhythmias, or intermittent output inhibition and bradycardia or asystole.
3. Failure to provide a minimum necessary heart rate due to an inability to produce a stimulus of sufficient strength or duration, resulting in loss of capture and bradycardia or asystole.
4. Failure of proper timing of output pulses resulting in an unanticipated, high rate or low rate of pacing which the patient may be unable to tolerate.

INDICATIONS, CONTRAINDICATIONS, WARNINGS AND POTENTIAL COMPLICATIONS, Continued

In the clinical setting, some of the above may additionally be attributable to user error in setting or adjusting the devices, to pacing lead displacement or breakage, and to faulty connections between pacing system components, ex. extension cables.

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

PROGRAMMABLE MODES AND PARAMETERS

Single Chamber Modes

AOO - Atrial Asynchronous Pacing

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

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 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.

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 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 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 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 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 Pacing (With Intact Atrial Sensing)

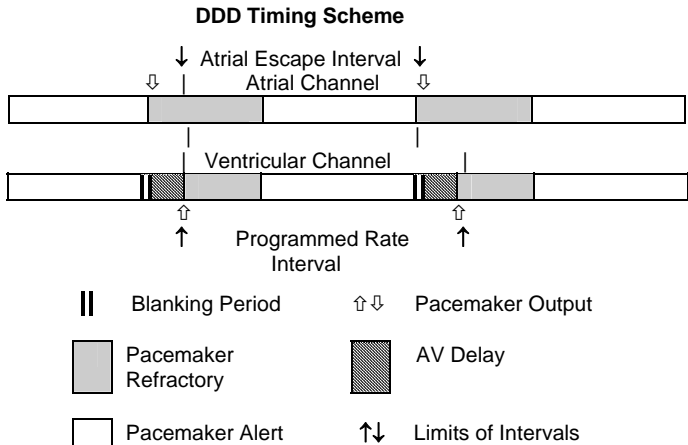
The capability for pacing and sensing is present in both chambers. However, sensed atrial activity will inhibit the atrial output pulse, but will not trigger a ventricular output pulse following the AV delay. DDI is a refinement of the DVI mode and will prevent competitive atrial pacing by maintaining atrial sensing. As with the DVI mode, AV sequential pacing at the programmed rate will be provided in the absence of intrinsic activity.

PROGRAMMABLE MODES AND PARAMETERS, Continued

Additionally, intrinsic ventricular activity occurring during the atrial escape interval or AV delay will inhibit the output 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 base rate 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.

DDD - Dual Chamber Atrial Tracking - 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 (PV) delay. Ventricular activity during the programmed AV delay will inhibit the ventricular output pulse, reset 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 and inhibit both output pulses. It will also begin a new atrial escape interval. As with the DDI mode, a ventricular blanking period occurs coincident with any atrial output pulse.



Parameters

Basic Pacing Rate

The AccuPace may be programmed from 30 ppm to 180 ppm in increments of 1 ppm in both single-chamber and dual-chamber modes. The programming of rates is unimpeded from 30 ppm to 180 ppm. To accomplish this with high rates, automatic adjustments are made in the refractory period(s) and / or AV delay. Each is shortened in sequence as the rate is increased and restored as the rate is slowed. In DDD, at a programmed rate of 180 ppm and a tracking limit of 220 bpm, the maximum AV delay will be 87 milliseconds. Any setting higher than 87 milliseconds will slowly drop to this value as the programmed rate reaches 180 ppm.

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.

PROGRAMMABLE MODES AND PARAMETERS, Continued

NOTE:

All Modes, when first turned On, start at 30 ppm. Rate can be changed, for all models, by using the Control Value, knob. If turned on by using the RESUME ON key the device will operate in the last operating condition.

Timing functions of an AccuPace are precisely determined by a crystal-controlled oscillator. As a consequence, there will be little difference between the rate of the AccuPace as programmed and displayed and that as determined by independent measurement of the pacing interval. An AccuPace is rate limited to 250 ppm in all modes except the Rapid Atrial Pacing Mode. For all models, the nominal rate for single-chamber modes is 70 ppm and dual-chamber modes is 60 ppm. These nominal values may be changed by the user following the instructions on page 18.

Pulse Amplitude

The pulse amplitude of the AccuPace pacing analyzer is programmable in steps of 0.1 volt from 0.1 to 10 volts. The standard value for output amplitude is 3.5 volts. This nominal value may be changed by the user following the instructions on page 18. 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 AccuPace analyzer is programmable from 0.05 millisecond to 1.0 millisecond in steps of 0.05 millisecond, and from 1.0 millisecond to 2.0 milliseconds in steps of 0.10 millisecond. The standard value is 0.40 millisecond. This nominal value may be changed by the user following the instructions on page 18. 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

Sensitivity may be programmed from a high of 0.5 millivolt on the atrial channel (1.0 millivolt on the ventricular channel) to 20 millivolts. From 0.5 to 10 millivolts, the value may be changed in steps of 0.5 millivolt. Above 10 millivolts, the step is 1.0 millivolt. The nominal value is 1.0 millivolt for the atrial channel and 3.5 millivolts for the ventricular channel. These nominal values may be changed by the user following the instructions on page 18. The sensitivity is independent of battery voltage, providing a constant sensitivity 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.

PROGRAMMABLE MODES AND PARAMETERS, Continued

AV Delay

The AV delay defines the time interval between an atrial output pulse and a ventricular output pulse. The range of AV delays that is available 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. The AV delay is programmable from 15 - 300 milliseconds in 1 millisecond steps. The standard value is 150 milliseconds. This nominal value may be changed by the user following the instructions on page 18. As previously stated, the AV delay will automatically shorten as the rate is raised toward its maximum value. The maximum value at a pacing rate of 180 ppm is 87 milliseconds.

NON-PROGRAMMABLE PARAMETERS

PV Delay

The PV delay is defined as the AV delay minus 25 milliseconds when the AV delay is set to a value from 50 to 300 milliseconds. At an AV delay below 50 milliseconds, the PV delay is auto-programmed, eventually becoming the same as the AV delay for settings equal to or less than 25 milliseconds, the minimum value for both AV delay and PV delay is 15 ms. This parameter is intended to create a distinction between the analyzer's response to the detection of a P-wave and its response to an atrial output stimulus such that the timing of the mechanical events remain similar in both instances. The nominal value of this parameter is 125 milliseconds. This feature is only associated with the DDD mode.

Refractory Periods

Pacemakers which operate in a sensing mode incorporate a feature known as the refractory period. Immediately following a output stimulus or an inhibiting 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, portions of the repolarization signal which might result in timing errors.

Single-chamber (AAI or VVI) refractory periods are 330 milliseconds. When the AccuPace is programmed to a dual-chamber sensing mode, there is a refractory period of 250 milliseconds for each sensing channel. At high rates, the refractory period is auto-programmed to facilitate device operation.

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. In dual-chamber sensing modes, references to the atrial refractory period always refer to the post-ventricular atrial refractory period, the 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 analyzer 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, output will be inhibited or triggered depending on the operating mode.

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 may be inadequate to prevent detection of "noise" associated with the output pulse, which may result in a recycling of the noise sampling period. When this is occurring, a dot will be seen alternating with the "A" or "V" enunciator, depending on whether an atrial or ventricular mode is programmed.

NON-PROGRAMMABLE PARAMETERS, Continued

Maximum Tracking Rate (Track Limit or Upper Tracking Limit)

The maximum tracking rate is a maximum of 40 ppm greater than the basic pacing rate and is only found in association with the AV Universal (or DDD) pacing mode. This parameter rises above its 100 ppm nominal or falls back to its low of 70 ppm in association with increases or decreases in the basic rate. The maximum is 220 ppm.

In the event the patient develops an atrial rhythm faster than the maximum tracking rate and the post-ventricular atrial refractory period (PVARP) does not prevent it, the analyzer 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 this 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 Total Atrial Refractory Period which is the sum of the AV delay and the PVARP.

Blanking Period

When an AccuPace analyzer 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 fixed at 30 milliseconds.

Ventricular Safety Pacing – DVI, DDI and DDD pacing modes only

Ventricular safety pacing is designed to prevent inappropriate inhibition of the analyzer's ventricular output pulse, if crosstalk occurs. This is accomplished by having the analyzer alert for crosstalk for a short period of time after the blanking period. The duration of the crosstalk detection window is equal to 64 milliseconds. The first 30 milliseconds of this period is coincident with the blanking period.

If a signal is sensed during the crosstalk detection window, the analyzer is triggered to deliver a ventricular output pulse 120 milliseconds after the atrial output pulse. Normal sensing is maintained after the crosstalk detection window, if no signal is detected in the crosstalk detection window. This feature is always operative in dual-chamber modes.

PVC Response

When an AccuPace is programmed to the DDD pacing mode, a protective response to the detection of a PVC is operative. The AccuPace will determine that a PVC has occurred, if it detects two ventricular events with no interceding paced or sensed atrial event. The analyzer responds to this event by reverting to DVI mode for a single cycle, thus eliminating the ability of the analyzer to track retrograde P waves. This is called the "DVI" response. The atrial channel remains refractory until the delivery of an atrial output pulse. Thereafter, normal DDD operation resumes.

PMT Limit

The pacemaker-mediated tachycardia (PMT) limit is fixed at 40 ppm greater than the programmed rate. It can be changed by changing the basic pacing rate.

NON-PROGRAMMABLE PARAMETERS, Continued

PMT Termination Algorithm

Whenever the AccuPace detects the presence of a potential pacemaker-mediated tachycardia operating at the tracking limit of the analyzer, defined as ten cycles at or above the PMT Limit (Track Limit), it will suspend atrial sensing for one base pacing cycle (DVI mode) in an attempt to break the PMT. If this attempt fails, the attempt will be repeated again 127 cycles later. If the attempt is successful, normal DDD pacing will resume. If not successful, the attempt is repeated every 127 cycles until it is successful.

GENERAL OPERATIONS

Power ON/OFF

The on and off keys are specialized for the convenience of the user and located below the display. To turn the AccuPace on in a specific mode, AAI, VVI, DVI or DDD, simply press the key for the mode desired.

To resume pacing in a previously programmed inhibited mode at the same parameter settings without disrupting measured data, press the [RESUME ON] key. To restore an asynchronous mode, press [RESUME ON] followed by a single press of the [ASYNCH/DEMAND] key.

The [STAT DDI] key may also be used to turn the AccuPace on. If this option is selected, the AccuPace comes on in DDI mode at high output settings. For standard settings, press the [NOMINAL] key.

To shut the AccuPace off, press the [OFF] key.

Special Features

The AccuPace contains a feature allowing the user to select the nominal values of the implantable pulse generator most commonly dealt with as those for the analyzer. This eliminates the need to make continual adjustments from some arbitrary nominal to the desired value each time the device is turned on. See "Adjusting Nominal Parameters", page 18.

The AccuPace will come on and establish pacing as quickly as possible. There is always one cycle of sensing prior to any pacing. An initial self-test sequence will occur at opportune moments during the first several pacing cycles without delaying the implementation of pacing.

If output pulses are being initiated by the AccuPace, the Pace/Sense indicators will be flashing "A" and "V". Any activity sensed on the atrial or ventricular leads will be flashed as "P" or "R", respectively. Under normal pacing conditions, combinations of all four may appear as flashing pairs of letters located in the upper left portion of the LCD display which describe exactly how the analyzer is responding in each cardiac cycle.

When the AccuPace is turned on, it immediately displays pacing mode, rate, AV delay, output amplitude, pulse width, sensitivity, rapid atrial rate, pacing / sensing event indicators and any status enunciators on the top line of the two line display.

For single-chamber modes, the output amplitude, pulse width, and sensitivity for the chamber being paced is displayed. For dual-chamber modes, the ventricular output amplitude, pulse width, and sensitivity will be displayed initially. The atrial data may be displayed by pressing the [ATRIAL/VENTR] key.

During normal operation, all lead measurement data will be displayed on the second line of the LCD display. However, when the analyzer is first turned on using a specific mode key, a special prompt is displayed on the bottom line. This prompt ensures that the user determines whether to proceed using previously stored data or whether to clear any old data. This step prevents the mixing of data from two different patients. The prompt is a two line message, alternately flashing, as follows:

"If New Patient Press [CLEAR DATA] Key"
"If Same Patient Press [RESUME ON] Key"

GENERAL OPERATIONS, Continued

This prompt does not delay or obscure pacing functions in any way. If the [CLEAR DATA] key is pressed, old data is stored in the archive and cleared from active memory, and the display reverts to the standard operational presentation. If the [RESUME ON] key is pressed, any prior patient test data will be retained as active. This step also makes it possible to retain the date and time information associated with a particular patient. In either case, pacing is commenced at nominal settings for the selected mode.

After the [CLEAR DATA] key is pressed at power on, the Patient ID may be entered along with any necessary adjustment of date or time via the MENU Operations beginning on page 17. This is not typically necessary. Entry of the Patient ID is an optional step which may aid identification of the record at a later time. The data as stored in memory always has a date and time annotation for identification purposes, regardless of whether it contains a more specific patient identifier. At times other than at power on, when the [CLEAR DATA] key is pressed the bottom line of the display will change to, "Press [CONFIRM] Key; Other Keys Cancel". In other words, when the [CLEAR DATA] key is pressed followed by pressing the [CONFIRM] key, any old data will be moved to memory and dashed lines will appear in the display location of each lead parameter indicating that no data has been taken. Patient ID is not cleared by pressing [CLEAR DATA], except in response to the prompt at power On.

Nominal (Standard Value) Pacing

To immediately return all operational parameters of an AccuPace analyzer to their nominal or standard values in the mode then programmed, press the [NOMINAL] key. The confirmation message, "NOTE: PACING VALUES SET TO NOMINAL", appears briefly in the display.

STAT (Emergency) DDI Pacing

Pressing the [STAT DDI] key changes the pacing parameters to STAT values (see page iii) and changes the mode to dual-chamber inhibited (DDI). Program execution is confirmed by the brief message,

"WARNING: ENABLING EMERGENCY DDI".

This mode is intended as one of the means which might be employed in an attempt to rapidly escape 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 environmental EMI with a low repetition rate. Flashing "P" and/or "R" enunciators on the LCD 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 asynchronous operation 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. To proceed with pacing in DDI mode at nominal settings, press [NOMINAL] after pressing the [STAT DDI] key.

Inhibit A or Inhibit V

With the AccuPace pacing analyzer connected to the patient's lead system, the atrial and/or ventricular output may be inhibited by pressing the [INHIBIT A-OUT] and/or [INHIBIT V-OUT] key. To resume pacing, simply press the appropriate key again. While output is inhibited, a unique two tone alarm will sound once a second. **The inhibit function should be used with caution in a patient with complete heart block (CHB).**

GENERAL OPERATIONS, Continued

Temporary Maximum Output

To speed the process of evaluating the risk of precipitating diaphragmatic stimulation at high output levels, the AccuPace is provided with a special key, [MAX OUTPUT]. When this key is pressed and held, pacemaker output for the channel displayed is raised to the maximum output amplitude of 10 volts and the maximum pulse width of 2.0 milliseconds accompanied by a unique two-tone alarm. Upon release of the key, the previously programmed settings return. To test the other output channel, first press the [ATRIAL/VENTR] key once to select the alternate lead.

MENU OPERATIONS

The [MENU] key allows the user to access optional resources which expand the capabilities of the AccuPace, but which are not typically necessary or which are not mandatory for a successful outcome. These individual items are selected by turning the CHANGE VALUE Wheel. The sequence in which the selections appear is the same as the list of menu options appearing below.

Atrial and Ventricular Capture Data

When the user first presses the [MENU] key once, the bottom line of the display will revert to the first menu item, the calculated data associated with capture determinations for the atrial lead; the pulse current (mA), pulse energy (μJ), pulse charge (μC), and the impedance (Ω). The second selection is the capture threshold data for the ventricular lead. This is an information only display. Displayed data may not be altered except by repeating the capture test. Press the [MENU] key to return immediately to the default display and Operating Mode. If no key is pressed, Menu Options Mode will automatically default to the Operating Mode one minute following the press of the [MENU] key.

Audio

All audio sounds made by the AccuPace maybe turned On or Off by manipulating the MENU key. Simply follow instructions by manipulating the CHANGE VALUE key, chose On or Off and press CONFIRM key.

Patient Identification (ID)

Press the [MENU] key to obtain the first display of the Menu Options Mode shown in the lower display of the LCD. Use the CHANGE VALUE Wheel to scroll through the options until "Patient ID" appears in the display. Press the [CONFIRM] key to activate the parameter and allow entry or change of data using the CHANGE VALUE Wheel. After each character or digit selection, press the [CONFIRM] key to advance to the next character or digit. When completed, the user need only press the [MENU] key to return operation to the Menu Operations.

View Archive Information

Press the [MENU] key to obtain the first display of the Menu Options Mode shown in the lower display of the LCD. Use the CHANGE VALUE Wheel to scroll through the options until "View Archive Information" appears in the display. Press the [CONFIRM] key to activate the parameter and allow review of the archived files using the CHANGE VALUE Wheel. If a particular file is to be reviewed in detail, press the [CONFIRM] key again and use the CHANGE VALUE Wheel to review each line of data. When finished, the user need only press the [MENU] key once to make another selection using the CHANGE VALUE Wheel or twice to return operation to the Menu Operations. The data which is entered in archive may be printed on the hard copy report at any time by selecting the Record Number from the PRINT DATA Menu.

MENU OPERATIONS, Continued

Date and Time

Press the [MENU] key to obtain the first display of the Menu Options Mode shown in the lower display of the LCD. Use the CHANGE VALUE Wheel to scroll through the options until "Date" or "Time", as desired, appears in the display. Press the [CONFIRM] key to activate the parameter and allow entry or change of data using the CHANGE VALUE Wheel. Activation is indicated by the appearance of a cursor under the character/digit. After each character/digit selection, press the [CONFIRM] key to advance to the next character/digit. When completed, the user need only press the [MENU] key to return operation to Menu Operations. The data which was entered will be printed on the hard copy report and retained with the data in archived records.

NOTE: A lithium "coin-type" battery is used to power the internal clock of the analyzer. It will last 8 - 10 years and is not user serviceable. See page 27 for recommendations concerning product service, and page 29 for product disposal.

Adjusting Nominal Parameters

The user may choose to operate the AccuPace at nominal settings for pulse amplitude, pulse width, sensitivity, and rates which are other than those set at the factory. To select alternate values, press the [MENU] key to enter the Menu Options Mode. Use the CHANGE VALUE Wheel to scroll through the options until "Adjust Nominal Parameters" appears in the display. Press the [CONFIRM] key to allow the change of nominal parameter values by output channel using the keypad and the CHANGE VALUE Wheel in the customary manner. The channel displayed for change is determined by the mode programmed. The alternate channel may be selected by use of the [ATRIAL/VENTR] key. The nominal rate for single or dual channel operation may also be changed. In this selection, the [RATE] key acts as a toggle key. The mode selected, whether single-chamber or dual-chamber, determines which rate is initially displayed for change. To set a new nominal for the other, simply press the [RATE] key. The display will change allowing the alternate option to be set. When all changes have been made, the user need only press the [MENU] key to return operation to Menu Operations. The new data which was entered will be retained in the memory of the AccuPace.

Display Light (Backlight)

Press the [MENU] key to obtain the first display of Menu Operation Mode shown in the lower display of the LCD. Use the CHANGE VALUE Wheel to scroll through the options until "LCD Backlight: XX" appears in the display. Press the [CONFIRM] key to activate the option and turn the CHANGE VALUE Wheel to select "On" or "Off", as desired.

"Off" is intended for those well-lighted conditions where the backlight is unnecessary. As long as the batteries in the analyzer retain sufficient power, the display light will come on at power on. After one minute, the backlight automatically turns off. The light will turn back on with any key press or change in the position of the CHANGE VALUE Wheel. The ability to turn the backlight off was provided as a means of reducing power consumption and extending battery life.

CONNECTION TO PACING LEADS

Each Pace Line output cable of the Model 4800 pacing analyzer has a dual pin connector at one end and "alligator" clip connectors at the other. The cables are capable of accepting and holding standard pacing lead connector pins as well as typical surgical heart wires securely. Each pair of alligator clips is labeled as to chamber and polarity. Negative (–) is typically the distal tip of a lead and positive (+) is typically the proximal ring electrode. The Model 4801 pacing analyzer utilizes an adapter to connect the cables to the device. Refer to the instruction manual accompanying the adapter to obtain information regarding the type of cable required. Each Pace Line output cable of the Model 4802 pacing analyzer has a unique 2 pin Redel connector at one end and "alligator" clip connectors at the other. The cables are capable of accepting and holding standard pacing lead connector pins as well as typical surgical heart wires securely. Each pair of alligator clips is labeled as to chamber and polarity. Negative (–) is typically the distal tip of a lead and positive (+) is typically the proximal ring electrode.

Bipolar Configuration

With the AccuPace off, connect the pacing leads to the appropriate extension cable alligator clips, observing both output channel and polarity. With the AccuPace now connected to the pacing lead(s), the analyzer may be switched on. Pacing begins immediately, unless inhibited by the patient's native rhythm. Changes in the programmed settings or the mode may be made, following the instructions which begin on page 20.

Unipolar Configuration

With the AccuPace off, connect the pacing leads to the appropriate negative (–) alligator clip(s); connect the positive (+) alligator clips to an indifferent plate placed subcutaneously. With the AccuPace now connected to the pacing lead(s), the analyzer may be switched on. Pacing begins immediately, unless inhibited by the patient's native rhythm. Changes in the programmed settings or the mode may be made, following the instructions which begin on page 20.

Unipolar configurations employing a common indifferent are inherently sensitive to the potential for crosstalk when operated in dual chamber sensing modes. If safety pacing should occur as a result of crosstalk due to lead geometry, high atrial output, or high ventricular sensitivity, and it is not possible to eliminate the cause due to considerations involving the patient, independent indifferent electrodes for the atrial and the ventricular leads may need to be employed to achieve desired dual chamber pacing results. In the alternative, pacing and testing may be performed in an appropriate single chamber mode.

PROGRAMMING

Changing Mode

Any of the four mode keys may be used to change mode. All relevant pacemaker parameter settings of the previous mode will be carried forward to the new mode. If nominal settings are desired for a mode, press the [NOMINAL] key. If the [STAT DDI] key is used to change mode, outputs will be set to 10V and pulse widths to 1.5 ms automatically. All other parameters revert to factory nominal values.

When a mode key is pressed, the display will immediately show the new mode and related parameters. The mode actually takes effect at the beginning of the pacing cycle following the key press. This means that any pacing cycle in progress will be completed.

To change any sensing mode to continuous (asynchronous) pacing, press the [DEMAND / ASYNCH] key. This key will change any sensing mode to its corresponding non-sensing mode. If pressed a second time, the key will restore sensing to the mode.

Any lead data taken will be unaffected by mode changes. Lead data is always preserved, unless replaced by new data or until forced out of memory by data overflow.

Changing Parameter Settings

To change any parameter value, press the desired key to make a cursor appear on either side of the displayed value, denoting that the parameter has been selected. All parameter keys are located adjacent to the parameter's displayed value. Press the desired parameter key and use the CHANGE VALUE Wheel to select the new value. A parameter value change is implemented only once in each pacing cycle. If changes in the value are made rapidly during the pacing cycle, the last value displayed prior to commencement of the cycle will be implemented.

The CHANGE VALUE Wheel allows changes in a parameter to be made as quickly or as slowly as desired. The CHANGE VALUE Wheel has mechanical detents ("clicks") that can be felt as the wheel is turned. Each click will change the parameter value by one increment.

If a parameter is selected, but not changed for one (1) minute, the cursor will disappear, deactivating the parameter. Likewise, pressing a different parameter key will also deactivate a previously selected parameter and result in the activation of the current selection.

Changing Parameters Displayed

When the AccuPace is turned on, it immediately displays pacing mode, rate, AV delay, output amplitude, pulse width, sensitivity, rapid atrial rate, pacing/sensing event indicators and any status enunciators on the top line of the two line display. The data displayed for each chamber consists of pacemaker data and lead data. Pacemaker data consists of output amplitude, pulse width, and sensitivity settings. Lead data consists of lead impedance, current delivered, P/R wave amplitude, and slew rate.

PROGRAMMING, Continued

Changing Parameters Displayed: Continued

For single-chamber modes, the data for the chamber being paced is displayed. For dual-chamber modes, the ventricular data will be displayed initially. The atrial data may be displayed by pressing the [ATRIAL/VENTR] toggle key.

In a single-chamber mode, the lead data for the alternate chamber may be viewed by pressing the [ATRIAL/VENTR] key. However, no pacemaker data will be displayed concurrently as the programmed mode does not involve output or sensing in that chamber. Lead data will only be present, if it was taken in a previous mode. Note that no new data can be taken, unless the pacing mode is changed to involve the chamber of interest.

Rapid Atrial Stimulation

Rapid atrial stimulation may be initiated from any programmed mode by pressing the [RAPID ATRIAL] key adjacent to the displayed rapid atrial rate. A cursor will appear on either side of the value indicating that the parameter has been selected. At this point, the AccuPace will still be providing pacing output in the selected mode and at the basic programmed rate.

After the rapid atrial parameter has been selected, the rapid atrial rate may be changed prior to rapid pacing by turning the CHANGE VALUE Wheel. When the desired rapid atrial rate has been set, rapid pacing can be activated by pressing and holding the [PACE RAPID] key. As long as the [PACE RAPID] key is held, the analyzer will deliver stimuli at the displayed rate on the atrial channel. The rapid atrial rate may be changed while rapid pacing is taking place by turning the CHANGE VALUE Wheel. Changing rapid stimulation rate while rapid stimulation outputs are active is facilitated in 10 ppm steps as opposed to the nominal change condition whereas rapid stimulation rate is changed in 1 ppm increments.

When the [PACE RAPID] key is released, the unit will return to its normal pacing operation. Rapid Atrial Pacing may be performed from any pacing mode. The [PACE RAPID] key will cause rapid pacing ONLY if the [RAPID ATRIAL] key has been pressed to first select the rapid atrial function. Once selected, if no other key is pressed or no other changes are made, it will time-out in 60 seconds deactivating the function. If the [PACE RAPID] key is pressed at any time when the rapid atrial parameter is not active, there will be no response to the key.

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

TEST FUNCTIONS

Measuring Stimulation Threshold

In preparation for the Stimulation Threshold Test, make sure that the current pacing mode involves pacing in the chamber of interest. If necessary, the mode can be changed instantly using one of the mode keys. Next, make sure that the desired lead data is displayed. This can be done using the [ATRIAL/VENTR] toggle key. Finally, make sure that the analyzer is pacing the heart and not being inhibited by intrinsic activity.

To begin, press the [OUTPUT AMPLITUDE] key to activate the parameter. Gradually decrease the output, using the CHANGE VALUE Wheel, while observing the patient's ECG, until the ECG shows loss of capture. Immediately increase the output until capture is just regained. This is the stimulation threshold. If the data is to be retained in memory for later print out, press the CAPTURE [STORE] key. This key press will also automatically return the programmed output to its nominal value.

The output amplitude and pulse width settings that were active at the time the CAPTURE [STORE] key was pressed will be permanently stored and appear in the display in the positions labeled capture amplitude and pulse width. These readings will be retained in memory and displayed until they are replaced by new readings, using the CAPTURE [STORE] key, or until cleared using the [CLEAR DATA] key. All data is retained, even if the analyzer is turned off or the batteries removed. This way, any data taken may be examined or printed out at a later time.

Measuring P Wave and R Wave Amplitude and Slew Rates

In order to determine P or R wave amplitude, the AccuPace must be in a mode involving sensing in the chamber of interest and it must be properly sensing. If necessary, the mode can be changed instantly using one of the mode keys.

To initiate measurement of the P or R wave amplitude and slew rate, press and hold the P/R WAVE [MEASURE] key. This inhibits the output of the AccuPace and changes the sensitivity to its maximum value for the selected channel, allowing verification of the presence of an adequate intrinsic rhythm by observing the analyzer display or the patient monitor. Each sensed event will cause the readings for signal amplitude and slew rate to be updated on the display. If the readings on the display are satisfactory, release the P/R WAVE [MEASURE] key. This causes a return of normal pacing support, and holds the last measured values on the display and in memory. The readings are retained in memory until replaced by new readings or until cleared using the [CLEAR DATA] key.

Measuring Lead (Stimulation) Impedance and Current Delivered

In preparation to measure the lead impedance and the current delivered, first make sure that the current pacing mode involves pacing in the chamber of interest. If necessary, the mode can be changed instantly using one of the mode keys. Next, make sure that the desired lead data is displayed. This can be done using the [ATRIAL/VENTR] toggle key. Finally, make sure that the analyzer is pacing the heart and not being inhibited by intrinsic activity. If it is inhibited, increase the rate or temporarily shift to asynchronous pacing by using the [DEMAND / ASYNCH] toggle key.

To initiate measurement of the lead impedance and current delivered, press and hold the LEAD [MEASURE] key adjacent to the lead impedance and current delivered display. Whenever the AccuPace delivers an output pulse, the lead impedance and current delivered are determined, stored in memory, and displayed. Every output pulse will cause an update to this reading.

TEST FUNCTIONS, Continued

Measuring Lead (Stimulation) Impedance and Current Delivered: Continued

When the desired measured values have been achieved, release the LEAD [MEASURE] key. This causes the unit to stop up-dating the measurements and to retain the last measured values. These measurements are stored until replaced by new readings, or until cleared using the [CLEAR DATA] key. The values so obtained are based on the true average value of impedance and are more accurate than methods using single point of the pulse calculations.

NOTE: It is recommended that impedance measurements be taken using nominal output values. Taking impedance measurements at very low outputs may result in abnormally elevated values due to a disproportionate influence associated with polarization potentials.

Measuring Retrograde (VA) Conduction Time

This measurement is provided as an indication of whether a patient may be subject to retrograde (VA) conduction and, if so, what the typical conduction time is. This information can be useful in preventing pacemaker-mediated tachycardias in patients to be paced in the DDD mode.

NOTE: This test may take several seconds once the RETRO (VDI) [MEASURE] key is pressed and held. During the test sequence, there is only an audio indication that the test is running. Hold the key until a result appears on the display.

To test for potential VA conduction, the analyzer must be effectively in VVI mode. This is accomplished by automatically converting the mode to VDI when the operator presses and holds RETRO (VDI) [MEASURE]. This is VVI mode with active sensing occurring in both chambers, but stimulation only in the ventricle. Performance of this test also requires pacing in the ventricle at a rate greater than the native P and R rates. Thus, unless the rate is set higher, the test will automatically proceed at a rate of 100 ppm. Display messages will indicate whether the AccuPace was able to proceed with the test. If not, the user must then decide whether to manually raise the rate further in order to perform the test.

Once the measurement sequence is initiated, whenever the AccuPace paces the ventricle, after a 180 millisecond refractory period, it will sense in the atrium until the next output pulse. If a P wave occurs in the sensing interval, the analyzer will measure the time between the ventricular stimulus and the P wave. Simultaneously, the AccuPace measures the V-V and P-P intervals for constancy, allowing only a pre-defined threshold difference between any two readings. If the required test criteria cannot be achieved, the sequence will terminate with a display message, "INDETERMINATE", and no result. To repeat the test, release the RETRO (VDI) [MEASURE] key, then press and hold it again. When the required criteria are met, the display message, "VALID DATA" will appear followed by the presentation of the result on the display. Release the key. This measurement is retained until replaced by a new reading, or cleared using the [CLEAR DATA] key.

Storing and Clearing Data

All data is retained in memory and displayed until replaced by a new reading or until cleared by pressing the [CLEAR DATA] key. All data is retained, even if the analyzer is turned off or the batteries removed. This feature allows the pacing analyzer to be turned off temporarily in the middle of an implant procedure and then turned back on at a later time without losing data taken earlier. It also allows any data, current or archived, to be examined or printed out at a later time.

TEST FUNCTION, Continued

CAUTION: Shut off the AccuPace prior to replacing batteries. Loss of patient data and pre-set nominal values will result, if battery removal occurs while the device is turned on. For proper storage of current data, always turn the AccuPace off using the [OFF] key.

Each time the unit is turned on, EXCEPT when using the [RESUME ON] key, the user is required to choose between continuing using stored data or clearing stored data. The storage of data is an automatic function. If the [CLEAR DATA] key is pressed, all data will be cleared into archive files and a new patient will be assumed. At times other than at power on, when the [CLEAR DATA] key is pressed the bottom line of the display will read, "Press [CONFIRM] Key, Other Keys Cancel".

Whenever data is cleared, it is entered into a "first in, first out" archive. Memory space is capable of holding 12 standard data patient reports. Each report is identified by its date and time of archive as well as a patient number, if that has been entered (see page 12). Patient ID number and the date and time may be important in distinguishing reports on the same patient. Each time a record is stored in the archive after it is full, the oldest of the 12 records will be lost.

Pace Medical, Inc.
AccuPace
Dual-Chamber Pacing Analyzer

=====
Procedure Date: 1/30/2008 Time: 10:29 AM
Report Date: 1/30/2008 Time: 11:41 AM
=====

Patient ID: _____

Physician: _____
=====

ATRIAL LEAD

Model No.: _____ S/N: _____

Lead Manufacturer: _____

CAPTURE DATA

Pulse Width: ----- milliseconds
Voltage: ----- volts
Impedance: ----- ohms
Current: ----- milliamperes
Energy: ----- microjoules
Charge: ----- microcoulombs

SENSING DATA

Amplitude: ----- millivolts
Slew Rate: ----- volts/second

IMPEDANCE DATA

Impedance: ----- ohms
Current: ----- milliamperes
Energy: ----- microjoules
Charge: ----- microcoulombs
@ Voltage: ----- volts
@ Pulse Width: ----- milliseconds

=====
VENTRICULAR LEAD

Model No.: _____ S/N: _____

Lead Manufacturer: _____

CAPTURE

Pulse Width: ----- milliseconds
Voltage: ----- volts
Impedance: ----- ohms
Current: ----- milliamperes
Energy: ----- microjoules
Charge: ----- microcoulombs

SENSING DATA

Amplitude: ----- millivolts
Slew Rate: ----- volts/second

IMPEDANCE DATA

Impedance: ----- ohms
Current: ----- milliamperes
Energy: ----- microjoules
Charge: ----- microcoulombs
@ Voltage: ----- volts
@ Pulse Width: ----- milliseconds

=====
RETROGRADE CONDUCTION:

----- milliseconds @ ----- bpm

=====
End of Report

Figure 3 - Print-out Format

SAFETY FEATURES

The AccuPace Pacing Analyzer 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 pacing analyzer 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 an AccuPace, 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.

NOTE: 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 AccuPace should be removed from service and returned to the company for repair.

EFFECTS OF DEFIBRILLATION, ELECTROSURGICAL DEVICES

An AccuPace analyzer is designed to tolerate defibrillator discharges of up to 400 Joules across the body of a patient having leads connected to the device. Electrocautery (EC) / electrosurgical (ES) devices are capable of generating very powerful electromagnetic fields which can induce damaging currents in micro-electronic 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 AccuPace pacing analyzer may be seriously damaged by the inappropriate proximate application of electrocautery / electrosurgical devices, whether to the device or to leads connected to the device.

If the use of EC/ES equipment is planned on a patient connected to an AccuPace, it is recommended that such use be limited either to short bursts or that the AccuPace 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 noted be rigorously observed during the entire course of the procedure.

NORMAL MAINTENANCE

Cleaning and Disinfecting

As previously described, an AccuPace Pacing Analyzer is both durable and splash resistant. If cleaning is required, it is recommended that a cloth or sponge simply dampened (NOT WET) with warm water and a small amount of non-abrasive detergent (or appropriate disinfectant solution) be used to wipe the device clean. Rinsing is accomplished similarly, using a cloth or sponge dampened in clean water. No unusual maintenance is otherwise required.

WARNING: Do NOT immerse an AccuPace in cleaning or sterilizing solutions. Do NOT attempt to sterilize it by autoclaving (EtO or steam), ultrasonics or gamma irradiation. Such procedures will seriously damage an AccuPace.

LOW BATTERY INDICATOR AND REPLACEMENT

Use Only Fresh 9 Volt Alkaline or Lithium Batteries in the AccuPace

A typical AccuPace will operate continuously for approximately 21 hours with two 9V alkaline batteries (IEC Type 6LR61); actual time is dependent on use of the LCD backlight. Do not mix the use of alkaline and lithium batteries. Batteries which are not fresh may result in reduced operating time. Either Duracell Model MN1604 or ENGERIZER Model 522 are recommended.

If installed batteries are not of adequate strength to power the unit when first turned on, the unit will either: 1) provide a brief warning of low battery condition on the display and promptly shut down, or 2) fail to power up at all, if the batteries are drained. A low battery condition that develops during use will be indicated by the appearance of a prominent "L" on the status line in the display.

The AccuPace will typically operate for a minimum of one hour beyond the first indication of low battery. Nevertheless, it is recommended that battery replacement be carried out promptly. The printing function will not be allowed by the software once the low battery condition occurs.

It is recommended that fresh batteries be installed prior to each use and that batteries not be changed during use. To replace the batteries, **first turn the AccuPace off using the [OFF] key. This is essential to avoid loss of current patient data and pre-set nominal parameter values.** Open the battery compartment. Remove both old batteries and replace with new batteries oriented for proper polarity. Close the battery compartment securely. Always keep an adequate supply of fresh batteries on hand. At least some of this supply should be kept with the AccuPace in its carrying case. Remove device batteries prior to storage.

CAUTION: The AccuPace analyzer is designed to suspend operation when the battery voltage reaches a level at which safe operation can no longer be assured. The user should check for the low battery warning routinely, and replace the batteries at the first indication of low battery. Abrupt loss of operation will occur, if the low battery warnings are ignored.

CAUTION

DO NOT change batteries while the device is attached to a patient.

SERVICE

In the event your AccuPace Pacing Analyzer should fail to function in accord with its specifications for any reason, return it to Pace Medical, Inc., 391 Totten Pond Road, Waltham, Massachusetts 02451, USA or to the Authorized European Representative, APC Medical Ltd., Welwyn Garden City, England for repair. Please contact the Company in advance of a return for complete instructions. Be certain to enclose a letter or report detailing the problem encountered. **This is not a user serviceable product.** Refer to the terms of warranty on page 29. Please telephone the company at +1 (781) 890-5656 (Pace Medical, Inc.) or +44 (01707) 327641 (APC Medical Ltd.) for assistance or additional information.

CAUTION: DO NOT USE an AccuPace which has been dropped onto a hard surface. Regardless of an apparent absence of damage, hidden damage may have been sustained which may result in unexpected device malfunction. **Factory service is strongly recommended.**

STORAGE

The carrying case of the AccuPace affords considerable protection from accidental damage both while in transit and in storage. Select a storage location that is cool (about 20°C or 68°F) and dry. In no event should an AccuPace be stored, even temporarily, in a location where 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 an AccuPace with the batteries in place. Battery leakage may cause corrosion of the battery terminals and damage the device's electronics.

AccuPace ACCESSORIES

Additional or replacement accessory items for the AccuPace are available. Contact the company for more detailed information.

Model 4280	Pace Line Autoclavable Surgical Extension Cable; A=atrial; V=ventricular (Model 4800 ONLY).
Model 4220	Pace Line Single Use Surgical Extension Cable, 5 / Box (Model 4800 ONLY), outside U.S.A. ONLY .
Model 4250	Pace Line Single Use Surgical Extension Cable. 5 / box, (Model 4800 ONLY).
Model 4255	Pace Line Single Use Surgical Extension Cables 5 / box. (Model 4802 ONLY).
Model 4830	Pace Line Autoclavable Extension Cable with Universal Connector. Length 10 inches (25.4 cm). (Model 4802 ONLY).
Model 5280	Pace Line Autoclavable Surgical Extension Cable; A=atrial; V=ventricular (Model 4802 ONLY).
Model 4840	Pace Line Autoclavable Adapter. A Male Redel Connector on the device end and a Female Redel Connector on the patient end. Length 10 inches (25.4 cm). (Model 4802 ONLY).
Model 4835	Operator's Manual for AccuPace
Model 4840	Soft pack Carrying Case with Shoulder Strap

WARRANTY

<p>LIMITED WARRANTY FOR PACE MEDICAL, INC. AccuPace PACING ANALYZER.</p>
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Effective January 1, 2008

The Company warrants its AccuPace Pacing Analyzer to be free from defects in materials and workmanship for all models 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. Expendable items such as Carrying Case, 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.

END OF USE - PRODUCT DISPOSAL

For disposal of an AccuPace, it is recommended that the user return the device to the manufacturer for proper handling and recycling of its components - see Service on page 27.

PHYSICAL SPECIFICATIONS

Operating Conditions:	+10 ⁰ C to +40 ⁰ C; RH 30% to 70%
Storage Conditions:	-20 ⁰ C to +60 ⁰ C; RH less than 85%

AccuPace:

Size:	10.4" long x 6.3" wide x 2.6" thick 26.4 cm x 16 cm x 6.6 cm
Weight:	2.75 lbs. (1.2 Kg)
Exposed Materials:	ABS Plastic, polycarbonate and stainless steel
Display:	40 characters x 2 lines alphanumeric LCD with backlight
Controls:	28 membrane keys, 1 rotary control
Connectors:	Model 4800 Standard 1.25" spaced plug-in style connectors Model 4801 one unique 6 pin female Redel connector Model 4802 two unique 2 pin female Redel connectors
Batteries:	Replaceable: Two 9V alkaline batteries; IEC type 6LR61 Not User Replaceable: One 3V lithium "coin" battery
Battery Life:	Approximately 21 hours with alkaline batteries, dependent on backlight use; reduced times may be seen, if batteries used are not fresh.

DISCLAIMER – This Users Manual supersedes any and all manuals and marketing materials

Trademarks

AccuPace™ is a trademark of Pace Medical, Inc.
Pace Line™ is a trademark of Pace Medical, Inc.
Redel® is a registered trademark of Limo SA.
