DUAL CHAMBER PACING SYSTEM ANALYZER

USER MANUAL

♣ DDD Pacing System Analyser

Model: SVR – 100



SHREE PACETRONIX LTD.

Plot No. 15, Sector II,

Industrial Area,

Pithampur, Dist. Dhar 454775 (M.P.), INDIA Telephone: 07292-411105

Fax: 07292-2762728

E-mail: pacetronix@hotmail.com
Website: http://www.pacetronix.com

Revision History

Revision	Date	Change Description	
01	July 4th, 2015	IFU	
02	August 25th, 2020	User Information	

Explanation of Symbols:

Sr. No	Symbol	Symbol Explanation	
1.	<u>i</u>	Operating instructions	
2.		Type CF applied part.	
3.	X	Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations	
4.	:	Package contents	
5.		Product documentation	
6.	- XX °C - XX °F + XXX °F	Temperature limitation	
7.	SN	Serial number	
8.	•••	Manufacturer	
9.		Date of manufacture	
10.	H	DEFIBRILLATION-PROOF TYPE CF APPLIED PART.	
11.	<u>^</u>	General warning sign	
12.	* - 9V 6LR61	Battery	

Contents

1.	Gl	ENE	RAL DESCRIPTION	6
2.	PA	CK	AGE CONTENTS	7
3.	SA	FE'	ΓΥ FEATURES	7
4.	SP	EC	IFICATION	7
	1. J		hnical Data	
4	1.2		chanical Data	
4	1.3		ninal Values	
5.	FU	JNC	TION AND DESCRIPTION	10
5	5.1	Fun	ctional Indicators	10
	5.1	.1	Pacing	10
	5.1	.2	Sensing	10
	5.1	.3	Low Battery indication	10
5	5.2	Cor	trols	10
	5.2	.1 Ra	ate (ppm)	10
	5.2	.2	Width (mSec) (Pulse width / Pulse duration)	11
	5.2	.3	A Sens (mV) (Atrium Sensitivity)	11
	5.2	.4	A Output (Volts) (Atrium Pulse Amplitude)	11
	5.2	.5	Mode	12
	5.2	.6	AVI (mSec) (A-V Interval)	12
	5.2	.7	V Sens (mV) (Ventricle Sensitivity)	12
	5.2	.8	V Output (Volts) (Ventricle Pulse Amplitude)	13
	5.2	.9	Refractory Period	13
	5.2	.10	P/R Wave	13
	5.2	.11	Impedance	13
	5.2	.12	IPG (Implantable pulse generator)	13
6.	Ol	PER	ATING INSTRUCTIONS	14
C	5.1	On	Off Switch	14
C	5.2	Kno	b Controls	14
Ć	5.3	Den	nand and asynchronous Modes	14
C	6.4	Col	let terminals	14
C	5.5	P/R	Wave measurement	15
Ć	5.6	Imp	edance measurement	15
6	5.7	<i>IPG</i>	Testing	15

6.8	Lead placement	15
6.9	Battery replacement	16
7. M	ODE DEFINITIONS	17
8. DI	EVICE MAINTENANCE	19
8.1.	Cleaning	19
8.2.	Safety & Technical checks	19
9 W	ARNINGS	20
10 I	PRECAUTIONS	21
11 I	FURTHER INFORMATION	24
12 I	LIMITED ONE YEAR WARRANTY	24

1. GENERAL DESCRIPTION

The **PSA Model SVR-100 (Dual Chamber Pacing System Analyser)** offers short-term pacing to the patient with myocardial infarction or heart block. It helps in analyzing the electrode positioning in the heart of patient while implanting the permanent pacemaker.

In designing these analysers, the emphasis has been on producing a rugged battery powered analyser that is small and light enough to be comfortably used during implant.

Stimulation is indicated by synchronous flashing of 'PACE' & sensing is indicated by synchronous flashing of 'SENS'. The PSA MODEL SVR-100 can function in both demand and asynchronous modes with the selection of pacing rates between 30-140 ppm.



Figure: 01

Figure: 02 SEAR SIDE



24

2. PACKAGE CONTENTS

- PSA MODEL SVR-100
- One 9V Alkaline battery.
- Technical manual.
- Carrying case.

Note: Check the package prior to use.

3. SAFETY FEATURES

The Shree Pacetronix Model 'Indus' SSB 100 is designed to be reliable, simple to operate, and comfortable to hold. Safety features of SSB 100 include:

- Low Battery indicator.
- Pace & Sense display on LCD
- Pacing LEDS. for both Atrium & Ventricle.
- Safety cables.
- Electrostatic protection.
- Minimized susceptibility to electromagnetic and magnetic interference.

4. SPECIFICATION

The PSA MODEL SVR-100 is the result of longtime experience in development and production of cardiac pacemakers. PSA MODEL SVR-100 provides safe and effective heart stimulation indicated by rhythm and conduction defects, termination of bradycardias at the time of implant or exchange of a pacemaker.

The optimal conception of PSA MODEL SVR-100 provides an easy and safe application under consideration of all the necessary aspects of practice of the pacemaker-therapy. Stimulation is indicated by synchronous flashing of 'PACE' & Sensing is indicated by synchronous flashing of 'SENS'. Mains independence battery

operation provides a maximum on electric safety for both patient and user

4.1 Technical Data

PARAMETERS	VALUES		
Description of Pacemaker	Dual chamber pacing system analyser		
Rate	30 to 140 Min ⁻¹ (In steps of 2 ppm)		
Amplitude (A & V)	0.2 TO 12 Volts		
Sensitivity	ATRIUM 0.4 To 4.6 mV (in steps of 0.3 mV) VENTRICLE 2.0 To 16 mV (in steps of 1.0 mV)		
Mode	AOO,AAI, DOO, DAI, DDD,VDD ,VVI, VOO		
AV Delay	30 to 250 ms (in steps of 1 ms)		
Pulse Width	0.1 to 1.2 msec (in steps of 0.1 ms)		
Refractory	400 ms		
Battery Life	120 hrs (without backlight)		
Battery Chemistry	Duracell 9V PP3 Alkaline battery		
Polarity	Bipolar		
Indication	 Pacing Indication: Flashing LED's on the front panel for both A & V. Flashing 'PACE' for Atrial (left column) on LCD. Flashing 'PACE' for Ventricle (right column) on LCD. Sense Indication: No Flashing on LED's. Flashing 'SENS' for Atrial (left column) on LCD. Flashing 'SENS' for Ventricle (right column) on LCD. Flashing 'SENS' for Ventricle (right column) on LCD. 		
Low Battery Indicator	Replace battery as Low battery Indicator glows.		
Lead	PSA Cable		

4.2 Mechanical Data

PARAMETERS	VALUES
Length x Width x Thick	190 mm x 120 mm x 60 mm
Mass (gm)	550 gm (with battery)

4.3 Nominal Values

PARAMETERS	VALUES
Rate	70 ppm
Amplitude (A)	5.0 Volts
Amplitude (V)	5.0 Volts
Sensitivity	ATRIUM 0.8 mV VENTRICLE 3.0 mV
Mode	DDD
AV Delay	120 ms
Pulse Width	0.5 msec
Refractory	400 ms

5. FUNCTION AND DESCRIPTION

5.1 Functional Indicators

5.1.1 Pacing

Stimulation is indicated by synchronous flashing of display "PACE" once for every pulse delivered by the pacemaker.

Pacing Indication:

- 1. Flashing LED's on the front panel for both A & V.
- 2. Flashing 'PACE' for Atrial (left column) on LCD.
- 3. Flashing 'PACE' for Ventricle (right column) on LCD.

5.1.2 Sensing

Sensing is indicated by synchronous flashing of display "SENS" once for every pulse sensed by the Pacemaker.

Sense Indication:

- 1. No Flashing on LED's.
- 2. Flashing 'SENS' for Atrial (left column) on LCD.
- **3.** Flashing 'SENS' for Ventricle (right column) on LCD.

5.1.3 Low Battery indication

It is recommended to replace battery when Low battery Indicator LED glows.

Normally the display is at Full intensity when the battery condition is good. As soon as the battery voltage drops below 6V the Low Battery Indicators LED will glow.

5.2 Controls

All controls available are Rotary Knobs calibrated for the Parameter displayed.

5.2.1 Rate (ppm)

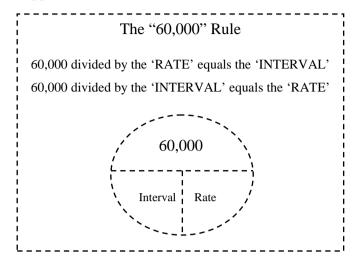
This knob is to select different rate values at which pacing pulses are delivered. It allows continuous adjustment of the rate from 30 to 140 ppm.

Description of Rate: The pacing rate refers to the average number of pacemaker's output pulses occurring over a specific period of time, usually one minute.

All controls available are Rotary Knobs calibrated for the Parameter displayed.



Rate (ppm) = 60000/ Interval (ms)



5.2.2 Width (mSec) (Pulse width / Pulse duration)

This knob is used to set Pulse width (ms) values. It allows continuous adjustment of the pulse width from 0.1 to 1.2 ms.

Description of Pulse width :-- The Pulse width or Pulse duration, is the measurement in time of the pacemaker output spike.

5.2.3 A Sens (mV) (Atrium Sensitivity)

This knob is used to set Atrium sensitivity (mV) values. It allows continuous adjustment of the Sensitivity from 0.4 to 4.6 mV.

Description of Atrium Sensitivity :-- Sensitivity is the ability of the pacemaker to see intrinsic cardiac events (P Wave).

5.2.4 A Output (Volts) (Atrium Pulse Amplitude)

This knob is used to set Atrium pulse Amplitude in volts values. It allows continuous adjustment of the amplitude from 1 to 12 Volts.

Description of Atrium Pulse Amplitude :-- It is the electrical pressure that causes electric current to flow.







5.2.5 Mode

This knob is used to set desired Mode. AOO, AAI, DOO, DAI, DDD, VDD, VVI & VOO

Description of Mode :-- This parameter defines the functionality of Pacemaker. It is defined by the 3 position NBG code as below :--



I	II	III	
Chamber(s) Paced	Chamber(s) Sensed	Mode(s) of Response	
O - None	O - None	O - None	
A - Atrium	A - Atrium	T - Triggered	
V - Ventricle	V - Ventricle	I - Inhibited	
D - Dual (A+V)	D - Dual (A+V)	D - Dual (T + I)	
S = Single (A or V)	S = Single (A or V)		

5.2.6 AVI (mSec) (A-V Interval)

This knob is used to set different A-V intervals in ms. It allows continuous adjustment of the A-V interval from 30 to 240 ms.

Description of A-V Interval :-- The set A-V Delay determines the time interval between an Atrial event (paced or sensed) and a Ventricular output pulse.



5.2.7 V Sens (mV) (Ventricle Sensitivity)

This knob is to select different Ventricle sensitivity values. It allows continuous adjustment of the Sensitivity from 2 to 16 mV.

Description of Ventricle Sensitivity :-- Sensitivity is the ability of the pacemaker to see intrinsic cardiac events (R Wave).



5.2.8 V Output (Volts) (Ventricle Pulse Amplitude)

This knob is used to set Ventricle pulse Amplitude in volts values. It allows continuous adjustment of the amplitude from 1 to 12 Volts.

Description of Ventricle Pulse Amplitude :-- It is the electrical pressure that causes electric current to flow.



5.2.9 Refractory Period

The Refractory period is the interval during which a sensed event does not affect pacing timing. The refractory period is fixed at appox. 400 ms and not displayed on LCD. PVARP is also fixed at approx. (Refractory period – A-V interval set value).

5.2.10 P/R Wave

This knob is to measure amplitude of P & R wave.

Description of P/R wave :--

- P Wave is intrinsic cardiac response of Atrium chamber.
- **R** Wave is intrinsic cardiac response of Ventricle chamber.

5.2.11 Impedance

This knob is to Measure Lead impedance.

Description of Impedance :-- It is the impedance of Lead & body. The acceptable range is 400 ohms to 1000 ohms.

5.2.12 IPG (Implantable pulse generator)

This knob is used to check a pacemaker.

Description of IPG:-- One IPG cable is provided with the DDDPSA. One end of the cables is connected to the pacemaker & other end to PSA. As we press IPG switch it will show Rate & pulse width of the Pacemaker if in working condition.







6. OPERATING INSTRUCTIONS

6.1 On / Off Switch

Switches the unit On and Off. (ON/OFF switch mounted on Rear panel of Unit).

6.2 Knob Controls

The available parameter range is printed on the panel, e.g the "Rate knob" ranges from 30 ppm to 140 ppm. Rotate the "knob" clockwise or anticlockwise to increase or decrease the parameters value respectively. Changed parameter value displayed on LCD screen accordingly.

Note:-

Parameters will be displayed as per the modes.

'Rate' & 'Pulse width' will be displayed in all modes.

Modes	Parameter Displayed	Parameter not Displayed
AOO	A-Amp	V-Amp, V-sense, A-sense, AVI
AAI	A-Amp, A-sense	V-Amp, V-sense, AVI
DOO	A-Amp, V-Amp , AVI	V-sense, A-sense
DAI	A-Amp, V-Amp, AVI, A-sense	V-sense
DDD	A-Amp, V-Amp, AVI, A-sense, V-sense	
VDD	V-Amp, A-sense, V-sense	A-Amp, AVI
VVI	V-Amp, V-sense	A-Amp, A-sense, AVI
VOO	V-Amp	A-Amp, V-sense, A-sense, AVI

6.3 Demand and asynchronous Modes

Demand Modes available are AAI > DAI > DDD > VDD > VVI Asynchronous Modes available AOO > DOO > VOO

Knobs turned clockwise select Mode starting from AOO > AAI > DOO > DAI > DDD > VDD > VVI > VOO

6.4 Collet terminals

Accepts External-pacing leads ranging from 1.8 to 2.3 mm diameter.

6.5 P/R Wave measurement

When measuring P/R wave amplitude the following parameters will automatically set to :

Mode = DDD, Rate = 40 ppm, AV Delay = 140 ms, Amplitude = 5 Volts (A & V both), Sensitivity = for 'A' 0.4 mV & for 'V' 2.0 mV. Press P/R wave button to measure P/R wave amplitude. If both or any one of the two channels are connected to heart and if it senses P or R wave, then the sensed P/R wave amplitude value will flash on the LCD (bottom), in place of flashing "Sens". P wave Amplitude will be displayed in line of 'Atrium' (printed on sticker) & R wave amplitude in line of 'Ventricle'. In case of no P/R sensing, it will flash 'PACE'.

6.6 Impedance measurement

It is the impedance of Lead & body. The acceptable range is 400 ohms to 1000 ohms. Press "Impedance" button to see impedance values of both Atrium & Ventricle. When measuring impedance the mode will be 'DOO' (in both dual & single chamber mode), base Rate 100 ppm, AV delay 140 ms, Amplitude 5V (in both A & V) and pulse width 1.0 ms

6.7 IPG Testing

Connect 'IPG' cable to BNC socket on the rear plate (marked IPG). Connect other end of the cable to the pacemaker. Press 'IPG' switch. If Pacemaker is working & its output is above 3V then Rate & Pulse width will be displayed. Otherwise 'no output or open' will be displayed.

6.8 Lead placement

- a). When positioning the lead in the heart it is recommended that the ECG should be monitored in order that the S-T segment elevation, indicating contact with the myocardium and impaction, can be noted.
- b). Connecting the lead to the PSA

Switch the PSA to OFF.

Connect the proximal electrode to the indifferent (+) red terminal and the distal electrode to the active (-) black terminal by using a PSA cable between Permanent lead and PSA as described in the method below.



Method: Twist the terminal caps counter clockwise, push the lead electrodes into the end of the collets terminals, tighten the leads by twisting caps clockwise.

Caution: The terminal caps should not be over tightened otherwise the terminal may break.

6.9 Battery replacement

It is recommended to replace battery when Low battery Indicator LED glows.

In the Low Battery case the unit will continue to pace normally, on the last set parameters but the battery should be replaced as soon as possible.

Under normal conditions at nominal values (see "Nominal values" section 4.3) of continuous operation, a 9V alkaline battery will have a service life of approximately 96 hours (4 days) on full battery.

NOTE: We recommend having a spare battery all the times. The battery should be removed if the device is placed in storage.

As an additional safety precaution the battery and contact terminals should be checked for corrosion at regular intervals. Use of other than the recommended batteries may result in one of the following conditions: (1) less than 24 hours of operation after the low-battery indicator comes on, (2) degraded pacemaker performance, and/or (3) overall reduced battery life.

7. MODE DEFINITIONS

Single Chamber Modes

The PSA MODEL SVR-100 will pace in 4 single chamber modes: AOO, VOO, AAI, and VVI.

A00 and VOO Modes

The asynchronous mode (A00 and VOO) emit a pacing pulse into one chamber, either the atrium (AOO) or the ventricle (VOO), at the end of the base rate interval, regardless of any intrinsic activity. When pacing in the A00 mode, the pacemaker will pace the atrium asynchronously at the programmed base Rate. The atria and ventricular channels are continuously blanked. When pacing in the VOO mode, the pacemaker will pace the ventricle asynchronously at the programmed base Rate.

AAI and VVI Modes

In the inhibited (or demand) modes (AAI and VVI), when an intrinsic beat is sensed outside of a refractory period and before timeout of the base rate interval, the pacemaker inhibits the output pulse. If no intrinsic beat is sensed before the timeout of the base rate, a pacing stimulus is delivered. When pacing in the AAI mode, the pacemaker will pace the atrium at the programmed base rate in the absence of detected atria activity. The ventricular channel is continuously blanked. When pacing in the VVI mode, the pacemaker will pace the ventricle at the programmed base **RATE** in the absence of detected ventricular activity. The atria channel is continuously blanked.

Dual Chamber Modes

The PSA MODEL SVR-100 will pace in four dual-chamber modes: DOO, DDD, DAI & VDD.

DOO Mode

When pacing in the A-V sequential asynchronous mode (DOO), the pacemaker will pace the atrium and the ventricle asynchronously at the programmed base rate and with the programmed A-V interval. Both channels are continuously blanked.

When the V-A interval times out, the pacemaker will:

- Start the A-V INTERVAL, and
- Deliver a pacing stimulus in the atrium.
- When the A-V interval times out, the pacemaker will deliver a pacing stimulus in the ventricle.

DAI Mode

In the Atrium demand A-V sequential (DAI) mode there is no ventricular sensing function. If a atria event is sensed outside of a refractory period, the pacemaker restarts the A-V interval. If a atria event is sensed after refractory period, the pacemaker inhibits the atrium stimulus.

DDD Mode

This mode provides a P-wave synchronous rate response with AV sequential pacing. Intrinsic activity in the atrium and ventricle inhibits output stimuli. Without atria events within certain periods, the pacemaker delivers a pacing stimulus to the atrium at the end of the V-A interval which is equal to the programmed base rate minus the programmed A-V INTERVAL. Without ventricular activity during certain periods, the pacemaker delivers a pacing stimulus to the ventricle at the end of the programmed A-V INTERVAL. The pacing rate can be limited by the UPPER RATE SO that the pacemaker does not pace the ventricle too fast in the presence of atria arrhythmias. When pacing in the DDD mode, the pacemaker will pace the atrium and the ventricle at the programmed base rate and with the programmed A-V interval in the absence of detected atria or ventricular intrinsic events.

VDD Mode

This mode does not provide stimuli to the atria. It senses the atral intrinsic activity, and pacemaker will deliver ventricle pacing stimulus at the end of the programmed **A-V INTERVAL**. This mode provides a P-wave synchronous rate response with AV sequential pacing. Intrinsic activity in the atrium and ventricle inhibits output stimuli. Without atria events within certain periods, Without ventricular activity during certain periods, the pacemaker delivers a pacing stimulus to the ventricle at the end of the programmed **A-V INTERVAL**. The pacing rate can be limited by the **UPPER RATE** SO that the pacemaker does not pace the ventricle too fast in the presence of atria arrhythmias. When pacing in the VDD mode, the pacemaker will pace the ventricle at the programmed base rate and with the programmed A-V interval in the absence of detected atria or ventricular intrinsic events.

8. DEVICE MAINTENANCE

8.1. Cleaning

DDDPSA

The PSA MODEL SVR-100 temporary pacemaker can be cleaned using a sponge or cloth moistened with water or 70% isopropyl alcohol.

Note: Do not expose the unit to ethers, acetone, or chlorinated solvents as these may damage the case or labels.

Caution: The PSA MODEL SVR-100 must not be immersed in water or cleaning agents. Severe damage to the device may occur.

Connecting Cables

The Patient Cables supplied are sterilized by ethylene oxide.

Prior to sterilization, Patient Cable should be cleaned thoroughly with a mild detergent or 70% isopropyl alcohol to remove all visible blood and body fluids. The cables may be immersed for cleaning. The cables must be thoroughly dried after cleaning. Inspection and testing by a qualified technician should be done after cleaning to verify proper cable function.

8.2. Safety & Technical checks

Safety and technical checks should be carried out *on the* PSA MODEL SVR-100 at least once every 6 months and after any malfunction or accident. Pacetronix does not recommend field repair of the device. For service or repair contact your local Pacetronix representative at the appropriate address.

9 WARNINGS

Equipment Modification

Do not modify this equipment. Modifications could impact device effectiveness and adversely affect patient safety.

Line-powered Equipment

An implanted lead or lead with extension cable constitutes a direct, low-resistance current pathway to the myocardium. Due to the danger of fibrillation resulting from alternating current leakage, extreme caution must be taken to properly ground all line-powered equipment used on or in the vicinity of the patient.

Electro surgery

Electro surgery can induce ventricular fibrillation, and thus should never be used within 15 cm (6 inches) of an implanted lead system.

Electromagnetic Interference (EMI)

All pacemakers operating in the demand mode respond to intra cardiac potentials of a magnitude of a few millivolts. They are inherently sensitive to some external fields. In the presence of excessive levels of interference the PSA MODEL SVR-100 may inhibit completely or revert to asynchronous operation, pacing at the rate set by the RATE knob. It is recommended that the device be set to an asynchronous mode when operated in the presence of strong electromagnetic interference (EMI).

Some sources of excessively strong EMI which may temporarily affect the operation of the PSA MODEL SVR-100 are:

- Electrosurgical equipment
- Diathermy equipment
- Some medical telemetry equipment (when operated within one meter [several feet] of the pacemaker).
- Communication transmitters such as cellular phones and "walkie talkies".
- Communication transmitters in emergency transport vehicles (in the presence of an active pacemaker) and
- Magnetic Resonance Imaging (MRI) equipment.

Defibrillation / Cardioversion

Defibrillation discharges of 360 watt-seconds have not affected the PSA MODEL SVR-100 in laboratory tests. However, for maximum safety it is recommended that the paddles not be placed near the PSA

MODEL SVR-100 or the lead system. Whenever possible, for the safety of the patient, disconnect the pacemaker from the lead system before defibrillating or cardioverting. A relatively low resistance pathway exists between the positive (+) and negative (-) electrodes of the implanted lead system. During defibrillation a large current could flow across this pathway, causing myocardial damage.

Connecting the Lead System

The patient cable should be connected to the temporary pacemaker before the lead system is connected to the patient cable.

Turning the Device On

Patient lead, cable and device connections should be made before the pacemaker is powered on.

10 PRECAUTIONS

General

Continuous ECG monitoring is necessary prior to pacing and during any pacing procedure. Facilities for defibrillation, I.V. infusion, end tracheal intubation and oxygen administration must be immediately available.

These miniature External pacemaker are protected against damage due to defibrillator procedures, but care should be exercised in the placing of the defibrillator electrodes away from the pacing leads.

Great care should be exercised when using diathermy in association with any cardiac pacing system. Adequate monitoring must be used.

Mains (Line) powered monitoring equipment is to be avoided when pacing, since even very less alternating leakage currents flowing through the heart may cause ventricular fibrillation. If mains (line) powered equipment is used, the manufacturers, or the person responsible for safety within your organization should be consulted on the safest method of connection.

The PSA MODEL SVR-100 described in this manual are not waterproof, and they must not be autoclaved or irradiated.

We recommend that only trained Pacetronix staff performs other repair and maintenance operations.

We recommend the External pacemaker should be checked for calibration at every six months interval.

CAUTION: The control knobs are individually calibrated. The External pacemaker will require to be re-calibrated if they are removed for any reason.

Random Failures

The physician should be aware that the PSA MODEL SVR-100 Temporary Pacemaker can fail due to a number of reasons, such as random component failure, battery depletion, and mishandling. Possible malfunctions of the PSA MODEL SVR-100 can include:

- No output
- No sensing
- False indicator light signals
- Increased or decreased rate, output pulse width, or output amplitude
- Reversion to asynchronous pacing and Loss of control of rate, output, sensitivity or power.

If loss of control of rate, output, sensitivity or power occurs, and it would be appropriate to temporarily stop pacing the patient, attempt to correct the condition by turning the device off and then on. If this does not correct the condition, remove the battery for 30 to 60 seconds, reinsert the battery, and turn the device back on.

Pacing Leads and Cables

Improper connection, displacement or fracture of leads or cables may also result in pacemaker system failure.

Lead Systems

Bipolar lead systems are recommended because they are less susceptible to electromagnetic interference.

Sensitivity Settings

Since the sensitivity setting determines the smallest signal that can be sensed by the pacemaker, set the sensitivity dial to at least one-half the mV value of the patient's sensitivity threshold. This will provide an adequate safety margin to ensure proper sensing. Be aware that setting the sensitivity value extremely low (the most sensitive) could result in inappropriate sensing of far field signals (e.g., sensing of R or T waves

on the Atrial lead or P waves on the ventricular lead), leading to

inappropriate inhibition of pacing pulses.

Electrostatic Discharge (ESD)

The pacing lead(s) provides a low-impedance pathway to the heart. Therefore, it is recommended that the attending health professional discharge any personal static electricity immediately prior to touching the patient, the cable, leads or pacemaker.

Termination of Pacing

Abrupt termination of pacing stimuli may result in periods of asystole before an intrinsic rhythm is established. Prior to terminating pacing, a gradual reduction in pacing rate, using the demand mode, is recommended.

Battery

Replace the battery for each new patient, and when the low battery indicator appears during device operation. Check the battery status at least twice daily. Replace alkaline batteries no less than every seven days during continuous use of the temporary pacemaker.

Use of batteries with different physical dimensions from that of the recommended batteries may result in erratic, or no pacing output. Inspect the contacts on the battery for visible signs of contamination prior to use. Use of batteries with contamination on the contacts may result in erratic, or no output. Failure to ensure that the battery drawer is fully latched may result in a loss of power.

Unauthorized Changes of Pacemaker Settings

Do not place the PSA MODEL SVR-100 in any area where patients may interact with it. The temporary pacemaker should be placed in an area that minimizes tampering with the device by unauthorized personnel (patients, visitors, etc.).

A-V Interval

Programming long A-V intervals may result in pacing the Ventricle during the vulnerable period of Ventricular re-polarization, thus precipitating ventricular arrhythmias in unstable patients.

11 FURTHER INFORMATION

For any further information please contact:

The Managing Director Shree Pacetronix Ltd. Plot No.15, Sector II, Pithampur, Dist. Dhar (M.P.) 454775

Fax: 07292 400418 Contact: 07292 411105

E Mail: pacetronix@hotmail.com Website: www.pacetronix.com

Notes:		

12 LIMITED ONE YEAR WARRANTY

PSA MODEL SVR-100

Dual Chamber pacing system analyser

1. Limited Warranty and Replacement Agreement: SHREE PACETRONIX LTD. provides assurance that if the PSA MODEL SVR-100 should fail to function within its specified tolerances within one year from date of purchase, due to faulty workmanship or a defective component excluding the battery, the Company will replace all components and provide service free of charge.

No warranty or replacement agreement whatsoever is made or given as to leads or adapters, battery and arm strap.

- 2. Limitation of Liability, Shree Pacetronix Ltd. shall not be liable for any medical expenses, adverse body reactions, or medical complications or other direct or consequential damages resulting from the use, removal or replacement of any pacing system analyser pursuant to this agreement or caused by any defect, failure or malfunction of the same lead or adapter, whether such claim for damages is based upon warranty negligence, contract strict liability tort or otherwise.
- 3. Disclaimer, this limited one year warranty is in lieu of all other warranties expressed or implied. Pacetronix specifically disclaims any implied warrantee of merchantability or fitness for a particular purpose. The remedies set forth herein shall be the exclusive remedies available arising out of the sale or use of the PSA MODEL SVR-100. No person has any authority to bind Shree Pacetronix Ltd. to any representation or warranty except as set forth herein.

Caution: Do not open the device this will void the warranty.