SINGLE CHAMBER EXTERNAL PACEMAKER

INDUS-I

MODEL : SSB-100

INSTRUCTION MANUAL

SHREE PACETRONIX LTD
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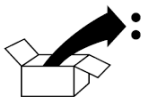
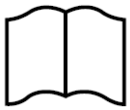
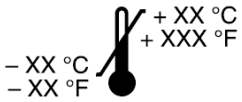
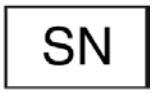
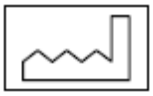
Revision History

Revision	Date	Change Description
02	January 8th, 2014	New EC Rep
03	August 21st, 2020	EC Rep & User Information
04	July 1st , 2021	Specification
05	Oct 20th , 2021	Specification

Explanation of Symbols:

Sr. No	Symbol	Symbol Explanation
1.		Operating instructions
2.		Type CF applied part.
3.		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.		Temperature limitation
7.		Serial number
8.		Manufacturer
9.		Date of manufacture
10.		DEFIBRILLATION - PROOF TYPE CF APPLIED PART.
11.		General warning sign
12.		Battery (9V , PP3)

Contents

1. General Description

The **Pacetronix Indus-I Model SSB-100** is a **Battery powered, Single Chamber cardiac pacemaker** designed primarily for temporary antibradycardia pacing therapy in asynchronous or demand (synchronous) modes. High rate burst pacing therapy tachyarrhythmias, is available in the asynchronous mode.

In designing these pacemakers, the emphasis has been on producing a rugged battery powered pacemaker that is small and light enough to be comfortably attached to a patient, yet possesses all the attributes of our reliable bedside units.

Stimulation is indicated by synchronous flashing of 'Red LED' & sensing is indicated by synchronous flashing of 'Green LED'. INDUS-I MODEL SSB-100 can function in both demand and asynchronous modes with the selection of pacing rates between 30 - 200 PPM. Over drive is also provided for terminating Tachycardia's. For overdrive the asynchronous mode has to be selected first and the rate knob will provide and increased frequency range from 80 PPM to 800 PPM. The push button is provided in the recess as a safety measure and can be operated by pressing it slightly.

In the presence of excessive level of electrical interference, the pacemaker will automatically switch from the demand mode (VVI) to a temporary asynchronous pacing mode (VOO) at the selected basic rate. Normal function is resumed when the level of interference is reduced.

a. Indications for use

Indus-I Model SSB-100 are single chamber anti-bradycardia external devices intended for temporary ventricular or atrial pacing applications. Their use may be indicated in the treatment of patients with deficient cardiac impulse generation systems or with deficient conduction.

b. Contraindications

There are not general contraindications to the use of ventricular pacing as a means of controlling heart rate. However, the patient's age and medical condition may dictate the particular pacing system and mode of operation used by the physician.

Indus-I Model SSB-100 devices are contraindicated for atrial pacing in the presence of an A-V conduction disturbance.

Indus-I Model SSB-100 devices are contraindicated for asynchronous pacing in the presence of competitive rhythms as well as in the presence of competition between paced and intrinsic rhythms.


Pacetronix
MODE VVI
RATE 140 PPM
AMP 4.5 V
INDUS - 1 SSB - 100
OD
ON
OFF
Pause
Mode (AOO-VOO)
Rate (30-200 bpm)
Amp (0.5V-12V)
Sense (mV)
Pace
Sens
Low Battery
CE

2. Package Contents

- Miniature external cardiac pacemaker type INDUS-I MODEL SSB-100.
- One 9V Alkaline battery.
- Instruction / Technical manual.
- Carrying case.

Note: Check the package prior to use.

3. Safety Features

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

- Low Battery indicator.
- Continuous operation during battery replacement.
  The battery change over time is approx 16 sec. to 20 sec.
- Protective covers over the controls and a rubber seal covering.
- Pacing and Sensing LEDS.
- Safety cables.
- Runaway rate protection;
- Electrostatic protection.
- Minimized susceptibility to electromagnetic and magnetic interference.

4. Specification

The external demand pacemaker INDUS-I MODEL SSB-100 is the result of longtime experience in development and production of cardiac pacemakers. INDUS-I MODEL SSB-100 provides a 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 INDUS-I MODEL SSB-100 provides an easy and safe application under consideration of all the necessary aspects of practice of the pacemaker-therapy. An Overdrive-Stimulation for terminating tachycardia is performed with the possibility of increasing the frequency. Stimulation is indicated by synchronous flashing of 'RED LED' & Sensing is indicated by synchronous flashing of 'GREEN LED'. Mains independence battery operation provides a maximum on electric safety for both patient and user.

4.1 Technical Data

PARAMETERS	VALUES	
Description of Pacemaker	External pacemaker	
Mode	AOO, AAI, VVI, VOO, Urgent	
Output Pulse Amplitude	0.1 to 18 Volts ± 10% *at 510 ohm Load*	
Detection of output pulse	Red LED flashes synchronously to every stimulation pulse.	
Pulse Width	1.50 ms ± 5%	
P/R Sensitivity	0.4 mV to 20 mV ± 20%	
Basic Pacing Rates	30 to 250 PPM	
Over Drive rates	60 to 1000 PPM ± 15 PPM	
Input Impedance	8 K Ohms ± 10%	
Refractory Period	UPTO 50PPM - - 500ms UPTO 70PPM - - 300ms UPTO 90PPM - - 250ms	UPTO 110PPM - - 200ms UPTO 130PPM - -180ms UPTO 250PPM - -150ms ±15% ***for all values***

4.2 Features

PARAMETERS	VALUES
Pause Button	Output will be paused for max. 10 sec. when pressed.
Lock	After every 20 cycles device will be locked automatically. To unlock press “Pause / Unlock” button.
ON / OFF Button	Separate ON and OFF button (Press OFF button twice to ‘switch off’ the device)
Noise detection	Signal >10Hz freq., Causes the device to switch to asynchronous stimulation mode (VOO).
Low Battery Indicator	• Continuous battery monitoring. • Change battery, when low battery indicator (Red

	LED) 'ON' • Battery replacement time approx. 50sec
Urgent Mode	Parameters: 80 PPM, 8 Volts
Defibrillation protection	Yes
Indication	**Pace Indication:** Flashing 'RED LED'. **Sense Indication:** Flashing 'GREEN LED'.
Buzzer	If Lead is open or short then buzzer will blow for every 16 cycle.

4.3 Mechanical Data

PARAMETERS	VALUES
Connection of Lead	1.8 to 2.3 mm Diameter
Dimension	200 x 110 x 32 mm
Weight	400 gm (with battery)
Operating Temperature	17^0C to 33^0C (64^0F to 92^0F)
Storage without Battery	5^0C to 70^0C (-40^0F to 158^0F)
Battery Life	200 hrs (At 60 PPM, 5 Volts)
Battery Chemistry	Duracell 9V PP3 Alkaline battery
Connection of Lead	Security sockets, 1.8 to 2.3mm Diameter
Enclosure Material	Acrylonitrile butadiene styrene

5. Function and Description

5.1 Functional Indicators

5.1.1 Pacing

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

5.1.2 Sensing

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

5.1.3 Low Battery indication

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

Normally the LED is OFF when the battery condition is good. As soon as the battery voltage drops below 6V the Low Battery Indicators LED will glow. In this condition the unit will continue to Pace, but it is recommended to change the battery as soon as possible. The Battery change over time is approx 50 ± 5 sec.

5.2 Controls

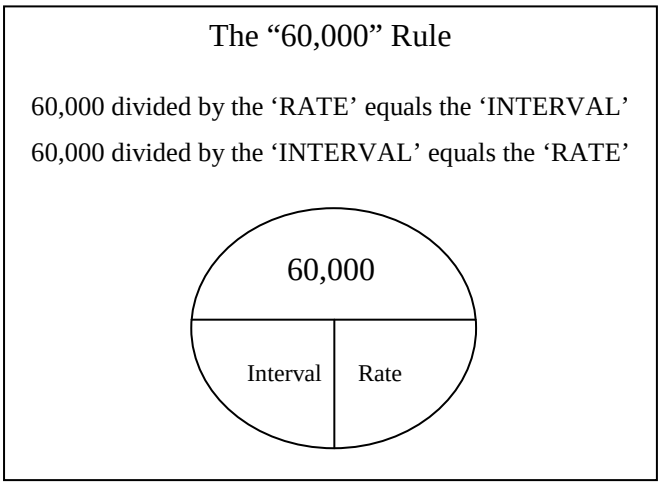
All controls available are Rotary Knobs calibrated for the Parameters.

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 250 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.

Rate (ppm) = 60000/ Interval (ms)



5.2.2 Output / Pulse Amplitude (Volts)

This knob is used to set pulse Amplitude in volts values. It allows continuous adjustment of the amplitude from 0.1 to 18 Volts.

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

5.2.3 Sensitivity (mV)

This knob is used to set sensitivity (mV) values. It allows continuous adjustment of the Sensitivity from 0.4 to 20 mV.

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

5.2.4 Mode

This switch is used to set desired Mode. Asynchronous and Demand

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 A - Atrium V - Ventricle D - Dual (A+V)	O - None A - Atrium V - Ventricle D - Dual (A+V)	O - None T - Triggered I - Inhibited D - Dual (T + I)
S = Single (A or V)	S = Single (A or V)	

Asynchronous. Mode :-- SOO / VOO / AOO
Demand Mode :-- SSI / VVI /AAI

6. Operating Instructions

6.1 On / Off Switch

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

6.2 Rate Controls

Adjusts the frequency at which pacing pulses are generated. The available pacing range is from 30 to 250 PPM. **Overdrive stimulation is also provided for terminating tachycardia. For overdrive, select asynchronous mode first and then push overdrive button to get pacing frequency range from 60 PPM to 1000 PPM.** The push button is provided in the recess as a safety measure and can be operated by pressing it slightly with any pointed stick.

6.3 Sensitivity Control

Adjusts the P/R wave sensing level. The sensitivity level is ineffective when in “Asynchronous” mode.

6.4 Demand and Asynchronous Modes

This decides the mode of operation.

Demand Modes available are AAI / VVI
Asynchronous Modes available are AOO / VOO

6.5 Collet Terminals

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

6.6 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.

6.7 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 200 hours on full battery and device service life is 5 years.

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. Interference Rate, High Rate protection & O/D facility

7.1 Interference

When operating in the Demand mode, an excessive level of electrical interference (e.g diathermy or microwave ovens) will cause the pacemaker to switch automatically in "Asynchronous" pacing at the set rate (frequency). Normal function is resumed when the level of interference is reduced.

7.2 High Rate protection

If an electronic component failure occurs in the unit, the maximum high asynchronous rate is restricted to 200 PPM.

7.3 Over drive facility

Overdrive stimulation is provided for terminating tachycardia. For overdrive the 'Asynchronous' mode has to be selected first and the rate knob will provide an increased frequency range from 60 PPM to 1000 PPM after pressing the push button "OD".

If overdrove (O/D) button is pressed in demand mode, the unit will operate at runway limit of 200 PPM.

8. Mode definitions

Single Chamber Modes

The Model SSB 100 will pace in two single chamber modes: SOO & SSI.

SOO Modes (AOO) / VOO)

The asynchronous mode (A00 or 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**.** When pacing in the VOO mode, the pacemaker will pace the ventricle asynchronously at the programmed base Rate**.**

SSI Modes (AAI / VVI)

In the demand mode (AAI or 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. When pacing in the VVI mode, the pacemaker will pace the ventricle at the programmed base rate in the absence of detected ventricular activity.

9. Device Maintenance

9.1 Cleaning

Single Chamber External Pacemaker

The Model SSB 100 external 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 Model SSB 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.

9.2 Safety & Technical checks

Safety and technical checks should be carried out *on the* Model SSB 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.

9.3.Device Disposal

Obsolete equipment should be returned to company for proper disposal. Medical equipment may be considered for disposal as a result of its natural obsolescence, failure to meet current treatment standards, poor serviceability etc.
As a minimum requirement the following steps should be taken –

1. Remove the outside case of the equipment.
2. Disassemble the unit.
3. The unit is then sent to stores as a rejection.

10. 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 Model SSB 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 Model Indus 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 Model SSB 100 in laboratory tests. However, for maximum safety it is recommended that the paddles not be placed near the Model SSB 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 external 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.

11. Precautions

General

Only authorized medical personnel must operate the INDUS-I MODEL SSB-100 Single chamber external Pacemaker.

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 pacemakers 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 miniature External pacemaker described in this manual is 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 Model SSB 100 external Pacemaker can fail due to a number of reasons, such as random component failure, battery depletion, and mishandling. Possible malfunctions of the Model SSB 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 external 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

To prevent unauthorized changes of pacemaker settings, the device is protected with a cover.

12. Further information

For any further information please contact :

SHREE PACETRONIX LTD.

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Pithampur, Dist. Dhar (M.P.) 454775
Contact: 07292 411105
Fax: 07292 400418
Email: pacetronix@hotmail.com
Website: www.pacetronix.com

Notes:

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13. Limited One Year Warranty

Indus – I MODEL – SSB 100

External Pacemaker

1. Limited Warranty and Replacement Agreement: SHREE PACETRONIX LTD. provides assurance that if the SSB 100 external Cardiac Pacemaker 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 SSB 100 external Cardiac Pacemaker. No person has any authority to bind Shree Pacetronix Ltd. to any representation or warranty except as set forth herein.