DUAL CHAMBER

EXTERNAL PACEMAKER

ZEUS - 1

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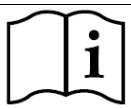
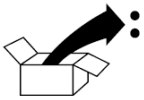
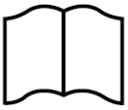
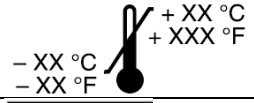
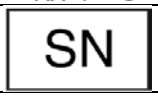
Revision History

Revision	Date	Change Description
01	January 15th, 2019	IFU
02	August 21st, 2020	User Information
03	October 20th, 2021	Specification & Sticker

Document: Man_Zeus-1, Rev 03 / 20102021

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

Contents

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1. GENERAL DESCRIPTION

The **Zeus-1** Dual chamber external pacemaker offers short-term pacing to the patient with myocardial infarction or heart block.

Note: In rest of the document Zeus-1 Dual chamber external pacemaker will be referred as Zeus-1.

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 reliable bedside units.

Stimulation is indicated by synchronous flashing of ‘PACE’ & sensing is indicated by synchronous flashing of ‘SENS’. The Zeus-1 can function in both demand and asynchronous modes with the selection of pacing rates between 30 to 200 ppm.

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.

ZEUS -1


– A + + V –
RATE 70 MOD DDD
AVI 20 ARF 250
AP 5.0 VP 5.0
LOCK
Zeus - 1
Dual Chamber External Pacemaker
Pacetronix
RAP: 80 - 800
Rate (30-200 bpm)
RAP
Mode (AOO-VOO)
URG
ON
AVI (20 - 300 ms)
Aref(150-500ms)
OFF
Amp (0.5-12V)
Amp (0.5V-12V)
Pause
Sense (mV)
Sense (mV)
Pace
Sens
Atrium
Low Battery
Sens
Pace
Ventricle
CE 1023

2. PACKAGE CONTENTS

- Zeus-1 Dual chamber external pacemaker.
- One 9V alkaline battery.
- Instruction / Technical manual.
- Carrying case.
- One Arm strap.

Note: Check the package prior to use.

3. SAFETY FEATURES

The Shree Pacetronix Model ‘ZEUS-1’ is designed to be reliable, simple to operate, and comfortable to hold. Safety features of ZEUS-1 include:

- Low Battery indicator.
- Continuous operation during battery replacement.
  The battery change over time is approx 15 sec..
- Rubber seal covering for box.
- Pacing/Sensing LEDS for both Atrium & Ventricle.
- Safety cables.
- Defibrillator and Electrostatic protection.
- Minimized susceptibility to electromagnetic and magnetic Interference.

4. SPECIFICATION

The Dual chamber external pacemaker Zeus-1 is the result of longtime experience in development and production of cardiac pacemakers. Zeus-1 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 Zeus-1 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 '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
Technical Parameters	
Description of Pacemaker	Dual chamber External Pacemaker
Rate	30 to 250 BPM (In steps of 2 BPM)
Upper Rate	Base Rate + 30 BPM (Min 110 BPM)
Rapid Atrial Pacing	60 to 1000 BPM
Amplitude (A)	0.1 TO 18 Volts (at 510 Ω load)
Amplitude (V)	0.1 TO 18 Volts (at 510 Ω load)
Sensitivity	ATRIUM 0.4 To 10 mV VENTRICLE 0.8 To 20 mV
Mode	AOO,AAI, DOO, DVI,DDI, DDD,VDD ,VVI, VOO
AV Delay	20 to 300 ms
Pulse Width	1.0 -- 1.5 ms
V Blanking Period	125 ms(Pace),75ms(Sense)
Refractory (PVARP in DDD)	Atrium 150-500ms, Ventricle 250ms
Battery Life	166 hrs
Battery Chemistry	Duracell 9V PP3 Alkaline battery
Polarity	Bipolar
Indication	**Pacing Indication :** Flashing RED LED's on the front panel for both Atrial & Ventricle. **Sense Indication :**

	Flashing GREEN LED's on the front panel for both Atrial & Ventricle.
Low Battery Indicator	Replace battery as Low battery Indicator (RED LED) glows. Battery Replacement time approx 15 Sec.
Buzzer Alarm	For lead integrity

Lock / Unlock	After 20 pacing/Sensing cycles device locked automatically. Press “Pause” switch to ‘Unlock’
Safety Cover	Acrylic transparent cover
Pause Button	When pressed output will be stopped for at the most 10 sec.
ON/OFF Button	Separate ON and OFF button to start and stop the device.
Lead	Temporary lead

4.2 Mechanical Data

PARAMETERS	VALUES
Length x Width x Thick	200 mm x 110 mm x 32 mm
Mass (gm) and Volume cc	400 (with battery) and 704 cc
Connection of Lead	Security sockets, 1.8 to 2.3mm Diameter
Enclosure Material	Acrylonitrile butadiene styrene

4.3 Urgent Values

PARAMETERS	VALUES
Rate	80 ppm
Amplitude (A)	10.0 Volts
Amplitude (V)	10.0 Volts
Mode	DOO
AV Delay	140 ms
Pulse Width (A/V)	1.0 ms / 1.5 ms

5. FUNCTION AND DESCRIPTION

5.1 Functional Indicators

5.1.1 Pacing

Pacing Indication :

Flashing LED's on the front panel for both A & V.

Note : These LED's indicate delivery of a pacing pulse but do not necessarily indicate that the pacing pulse has initiated cardiac stimulation.

5.1.2 Sensing

Sense Indication :

Flashing LED's on the front panel for both A & V.

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. Battery Replacement time is approx.15 Sec.

5.2 Controls

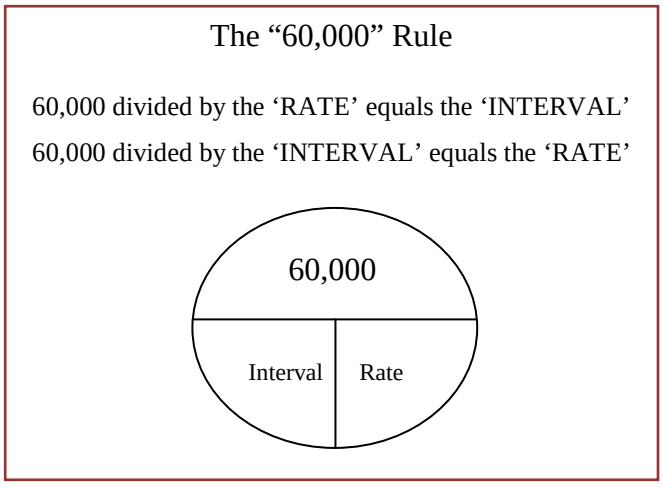
All controls available are Rotary Knobs calibrated for the Parameter displayed.

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 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 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 20 to 300 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

Note: If A-V interval is set shorter than blanking period set value than Ventricular events may not be sensed. Also AV interval cannot be less than blanking period. AVI less than 90 ms can be set in DOO mode only.

5.2.3 '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 0.1 to 18 Volts.

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

5.2.4 '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 10 mV.

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

5.2.5 Mode

This knob is used to set desired Mode. AOO, AAI, DOO, DVI, DDD, VDD, VVI , VOO and Urgent.

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/ V)	S = Single (A/ V)	

5.2.6 Refractory Period (A & V)

The Refractory period is the interval during which a sensed event does not affect pacing timing. **The Ventrical refractory period is fixed at appox. 250 ms.** Knob is used to set Atrial refractory period (ms). It allows continuous adjustment of A Ref period from 150 to 500 ms. This is PVARP (Post ventricle Atrial refractory period) for dual chamber modes.

Description of Blanking period : Blanking is the period following a paced Atrial event for which Ventricle sense amplifier will be kept 'OFF'.

5.2.7 '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 0.1 to 18 Volts.

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

5.2.8 'V' Sens (mV) (Ventricle Sensitivity)

This knob is to select different Ventricle sensitivity values. It allows continuous adjustment of the Sensitivity from 0.8 to 20 mV.

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

5.2.9 Blanking Period

Blanking is the period following a paced Atrial event for which Ventricle sense amplifier will be kept 'OFF'. Blanking period is fixed For Pace- 125ms and for Sense-75ms.

5.2.10 Rapid Atrial Rate

Caution: RAP is for atrial use only. Be sure the leads are connected to the atrium, not the ventricle, before enabling RAP.

Rapid atrial rate is used to control Atrial fibrillation. Rapid atrial rate can be activated by pressing RAP button located on front panel of the unit and by selecting from rate setting knob.

Caution: RAP may result in tachycardia, acceleration of existing tachycardia, or fibrillation. Apply high rates under careful patient monitoring and control. Monitor the patient's ECG and

blood pressure, and ensure defibrillation equipment is immediately available.

6. OPERATING INSTRUCTIONS

6.1 RAP Button

Whenever Rapid Atrial Rate is required, press the RAP button and adjust the rate knob for desired Atrial rate.
Caution: Only for Atrial

6.2 ON Switch

Switches the unit ON by pressing ON button.

6.3 OFF Switch

Switch the unit OFF by pressing OFF switch twice in 4 sec. Press and held switch for 1 sec and then release and press again. If it doesn't gets OFF then repeat the process.

6.4 Pause / Unlock Button

Pause button is used to stop output of the unit for both chambers. (When pressed and held the output stops for at the most 10 seconds). If pause is required again after 10 seconds, then release button and press again.

6.4.1 **Device LOCK**

Alternate function of this button is to unlock the device. The device will go in LOCK mode after 20 pacing/sensing cycles if the device is kept idle. The message "LOCK" will appear on the display along with other parameters. After this parameters will not be changed even after moving rotary switches. To unlock the device press "Pause" button once then "LOCK" message will disappear and now parameters can be changed.
Press "PAUSE" switch to "UNLOCK"

NOTE: Please make sure after unlock all the parameters are at safe values as after unlock parameters will be set as per rotary switches position because as the rotary switch is rotated in LOCK condition then device will set values after UNLOCK it.

6.5 Knob Controls

The available parameter range is printed on the panel, e.g the "Rate knob" ranges from 30 ppm to 250 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,Aref
AAI	A-Amp, A-sense,Aref	V-Amp, V-sense, AVI

DOO	A-Amp, V-Amp , AVI	V-sense, A-sense,Aref
DVI	A-Amp, V-Amp, AVI, V-sense	A-sense
DDD	A-Amp, V-Amp, AVI, A-sense, V-sense,Aref	-----
VDD	V-Amp, A-sense, V-sense, Aref	A-Amp, AVI,
VVI	V-Amp, V-sense	A-Amp, A-sense, AVI,Aref
VOO	V-Amp	A-Amp, V-sense, A-sense, AVI, Aref

6.6 Demand and asynchronous Modes

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

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

6.7 Urgent Mode

For urgent mode setting turn mode selection knob clockwise to extreme right.

6.8 Collet terminals

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

6.9 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 ZEUS-1

Switch OFF the device (Zeus-1).
Connect the proximal electrode to the indifferent (+) red terminal and the distal electrode to the active (-) black terminal of Temporary lead

and External pacemaker (Zeus-1) 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.

6.10 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 of continuous operation, a 9V alkaline battery will have a service life of approximately 166 hours (7 days) on full battery.

Nominal Values: Mode- DDD , Rate – 70 BPM , Amp (A/V) – 5.0V AVI – 140 ms, Sens (A/V) – 0.8mV/2.0mV

NOTE: We recommend having a spare battery all the times. The battery should be removed if the device is placed in storage. **Battery replacement time is approx 15 seconds.**

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 Model Zeus-1 will pace in four single chamber modes: AOO, VOO, AAI, and VVI.

AOO 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 Model Zeus-1 will pace in four dual-chamber modes: DOO, DDD, DVI & 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.

DVI Mode

In the Ventricle demand A-V sequential (DvI) mode there is no atrium sensing function. If a ventricle event is sensed outside of a refractory period, the pacemaker restarts the V-A interval. If ventricle event is sensed during AV interval then the pacemaker inhibits the ventricle stimulus.
Note:
PVARP and **UPPER RATE** do not apply in this mode.

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

Zeus-1 Temporary Pacemaker

The Model Zeus-1 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 Model Zeus-1 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* Model Zeus-1 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 Model Zeus-1 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 Zeus-1 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 Zeus-1 in laboratory tests. However, for maximum safety it is recommended that the paddles not be placed near the Model Zeus-1 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 .Before connecting to patient parameters should be verified.

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 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 Zeus-1 Temporary Pacemaker can fail due to a number of reasons, such as random component failure, battery depletion, and mishandling. Possible malfunctions of the Model Zeus-1 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 Model Zeus-1 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 :

Shree Pacetronix Ltd.

Plot No.15, Sector II,

Pithampur, Dist. Dhar (M.P.) 454775

Fax: 07292 400418

Tel: 07292 411105

Email: pacetronix@hotmail.com

Website: www.pacetronix.com

Notes:

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12 LIMITED ONE YEAR WARRANTY

ZEUS-1

---- Dual Chamber External Pacemaker -----

1. Limited Warranty and Replacement Agreement: SHREE PACETRONIX LTD. provides assurance that if the 'ZEUS-1' Dual chamber external 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 external pacemaker 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 'ZEUS-1' Dual chamber external pacemaker. No person has any authority to bind Shree Pacetronix Ltd. to any representation or warranty except as set forth herein.

Note: The expected service life of the device is 5 years.
Caution : Do not open the device this will void the warranty.