

USER INSTRUCTION MANUAL

Micropace Cardiac Stimulators

EPS320B/BT StimCor™ StimLab™

(E 2797

Distributed by:

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AND

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www.micropaceEP.com/euar.html

CAUTION US Federal Law restricts this device to sale by or on the order of a physician.

> **Micropace Cardiac Stimulators User Instruction Manual**

EPS320 & StimCor™ & StimLab™ Micropace Part Order No. MP3425 Compact Version English V1.6, 11/04/2023

Valid for:

Stimulator Software version 4.0 SGU Firmware versions 4.76

https://micropaceep.com/customer-support/downloads/



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Glossary and Terms

Term	Explanation
Drive Train	Also called S1; the 6-8 regular pacing stimuli before any extra-stimuli is applied.
ECG	Electrocardiogram
EP	Electrophysiology
IECG	Intra-cardiac Electrocardiogram
LCD	Liquid Crystal Display
LED	Light Emitting Diode
P/QRS	P wave or QRS; also signifies any IECG waveform.
PC	Personal Computer
RA	Right Atrium
RV	Right Ventricle
RF	Radiofrequency, e.g. RF Ablation
RR	R-R interval on ECG or peak-to-peak interval on IECG.
S1	Basic stimulation interval.
SGU	Micropace Stimulus Generator Unit
SM-Box	Stimulus Multiplexer Box – converts EPS320 two stimulus output channels to four channels.
SNRT	Sinus Node Recovery Times
StimLink™	Communication cable for connection to EP Recording Equipment
Sx	The name for and the coupling interval of one or more extra-stimuli added after Drive Train called S2, S3S7.
GUI	Graphical User Interface

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1 Introduction & Essential Prescribing Information

1.1 Device Description

1.1.1 Description of Stimulator

Micropace cardiac stimulator systems are all based on the EPS320 cardiac stimulator, a diagnostic external programmable cardiac stimulator.

The description of each system is described in its own section below.

1.1.2 Accompanying Documentation

- □ User Instruction Manual (Instructions for Use), this document.
- □ Technical Description, which includes installation instructions and advanced usage information (English-only, included in full English UIM MP3395).
- Accessories Unit Contents and Instructions for Use Leaflet
- Service Manual is available on request

It is strongly recommended that the Operator reads the User Instruction Manual document in its entirety and is familiar with its contents before using the Stimulator on patients.

1.1.3 Intended Use

The Micropace Cardiac Stimulator is intended to be used for diagnostic electrical stimulation of the heart for the purpose of initiation and termination of tachyarrhythmias, refractory measurements and measurements of electrical conduction.

1.1.4 Indications for Use

The Stimulator system is an electrical stimulus generator for diagnostic cardiac stimulation during electrophysiological testing of the human heart.

1.1.5 Operating Environment

The stimulator is intended for use in air conditioned hospital cardiac electrophysiology laboratories equipped for advanced cardiac resuscitation, by technicians trained in diagnostic cardiac stimulation under constant supervision by a cardiologist. Stimulator parts Remote Station MP3168 and connection boxes MP3086 and MP3014 may be used in the patient environment, but must be protected from ingress of fluids. The required installation and electromagnetic environment is described in the Technical Manual.

Device is not intended for use with flammable gasses of liquids, no part of it is sterile or sterilizable and device is not protected from ingress of fluids.

Warning: Do not stack EPS320 components or use them directly adjacent with other equipment. If adjacent or stacked use is necessary, verify normal operation in the configuration per the system verification instructions in this IFU.

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1.1.6 Contraindications

Do not use the Stimulator system for life support in patients with life-threatening bradycardia; use instead temporary external pacemaker.

1.2 Compatible Equipment

The primary function of the Micropace Cardiac Stimulator is the generation of constant current rectangular stimulation pulses with amplitudes of 0.1 mA to 25 mA, duration of 0.5 ms to 10 ms and with a maximum voltage of \pm 27V. Third party switching equipment with the following special characteristics must be used to carry the stimulus pulses to the intracardiac electrodes without significant distortion:

- □ Series resistance: < 100 Ohms at up to ± 25mA
- □ Shunt resistance: > 100,000 Ohms at up to ± 27V
- □ Frequency bandwidth: DC to 300 Hz
- □ Interference RF energy sources: < 350Vpp at 400 kHz to 600 kHz, or 150W into a 300 Ohm load

Micropace Stimulator is intended for use with the following equipment;

Diagnostic and Ablation pacing electrode catheters

 Currently available legally marketed electrophysiological diagnostic electrode catheters, including those manufactured by Cordis Biosense Webster, Daig, CR Bard, Medtronic and EPT.

EP Recording equipment

□ Computerized EP Recording systems manufactured by Bard Electrophysiology (LabSystemTM DuoTM and LS ProTM) and GE/Prucka (CardioLab 4000, 7000) have been tested for use with the EPS320 Stimulator.

1.3 Important Patient Safety Warnings

1.3.1 General Warning

Warning: Stimulator must be used only under supervision by a cardiologist.

- To avoid death or injury to patient from arrhythmias, the Stimulator may be used on humans only under the direct supervision by a physician familiar with electrophysiology in an appropriate hospital facility.
- ☐ The supervising physician must verify all Stimulator settings immediately prior to commencement of pacing.

Warning: Installation and use only by qualified personnel.

- Only qualified personnel, such as representatives of Micropace Pty Ltd, its authorized distributor or hospital-appointed biomedical engineers, may carry out installation of the Stimulator system and its connection to other equipment.
- □ In order to reduce operator errors, installation, configuration and customer training should be performed in a manner, which allows optimal use of the Stimulator by the user.

Warning: Stimulator is not a life support device – operator must have available backup temporary external pacemaker.

□ To avoid injury to patient from bradycardia, operator must have available a backup temporary external pacemaker.

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Warning: Stimulator must use isolated mains supply only.

□ To avoid electrocution hazards, all parts of the Stimulator, including the computer, monitor and Stimulus Generator Unit must all be connected to the Mains Isolation Transformer and never directly to a mains power outlet.

Warning: To avoid electrocution hazards, connect Stimulator system only to legally marketed, mains-isolated electrical equipment.

- Connect Stimulator only to parts specified by Micropace as compatible or to equipment certified to IEC 60601-1.
- Do not connect equipment other than that specified by Micropace to the multiple socket outlets on the Micropace supplied Isolation Transformer.
- □ If this equipment is modified, appropriate inspection and testing, including IEC 60601-1:2005, must be conducted to ensure continued safe use of the equipment.
- Avoid connecting equipment parts to patient by touching simultaneously conductive part of this or other equipment and the patient.

Warning: Use Stimulator only in ventilated areas and away from flammable gasses.

□ To avoid risk of explosion, the Stimulator should only be used in a ventilated area as gasses may be released during charging of backup battery, and should not be used in rooms with flammable anesthesia.

1.3.2 Warnings Specific to the Micropace Stimulator

Warning: Monitor function of Stimulator and patient's vital signs continuously.

- □ The Micropace Stimulator may fail to stimulate or unintentionally stimulate the patient through software, hardware or human error. To avoid injury to patient from arrhythmias, monitor the function of Stimulator and patient's vital signs continuously while Stimulator is connected to the patient.
- □ In case of repeated recurrence of unexplained life-threatening arrhythmias despite cardioversion/defibrillation during the use of the Stimulator, disconnect the Stimulator from the patient by unplugging the green Pace Output plug on the front panel in case it has an occult malfunction causing recurrent micro-electrocution or recurrent DC current stimulation.

Warning: Measurements by Stimulator are for information only.

□ Measurements displayed by Stimulator, including the Impedance measurement, RR interval and SNRT measurement are for facilitation of use of Stimulator. The user should use third party legally marketed measurement devices independent of the Stimulator to measure these parameters for the purpose of clinical diagnoses.

Warning: When using the optional Four Channel Stimulus Multiplexer Box (SM-Box)

- Product is not suitable for sterilization and must be protected from ingress of fluids
- □ In order to prevent inadvertent or ineffective pacing, the user should always verify the actual channel being paced using independent EP Recording Equipment.

1.3.3 Warnings Related to the use of Micropace Stimulator with RF Ablation Equipment

Warning: Use Stimulator only with RF-filtered stimulus connection. (Micropace parts: MP3014, MP3086).

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- □ Use only supplied Stimulus Connection Box (MP3014) or optional Stimulus Multiplexer Box (MP3086) components to connect Stimulator's stimulus output to patient circuits.
- □ The MP3014 and MP3086 components are over voltage protected by gas arrestors for differential voltages > 350VAC. Exposing these components to unfiltered RF ablation energies exceeding this limit (e.g. by direct connection to unfiltered RF Ablation energies > 150W or ablating into > 300 Ohm loads may cause reduction of RF energy available for ablation and overheating and a fire hazard within these components.

Warning: Do not stimulate via ablation electrode during delivery of RF Ablation energy.

□ To avoid possibility of unintended arrhythmia induction, do not stimulate myocardium via the ablation electrode during application of RF energy. Efficacy and potential for adverse effects of stimulation of heated myocardium in the process of ablation have not been established.

1.4 General Precautions in Handling Stimulator

Caution: Installation, Transport, and Storage.

- □ To ensure reliable operation of the Stimulator, install it in a well-ventilated place away from dust, excessive heat or humidity, direct sunlight and splashing liquids.
- □ To ensure operator may see important error messages displayed during operation, install with the front panel of the Stimulus Generator Unit visible to the Operator.
- □ To avoid damage to the Stimulator, avoid exposure to chemical gases, excessive vibration, impact, temperatures above 60 Deg. Celsius or ambient air pressures equivalent to above 10000m altitude during transport and handling.
- To ensure that backup battery remains fully charged, store system between uses with the Stimulus Generator Unit connected to mains power supply, switched on at the rear panel switch.
- □ Assembly and modification of this Medical System during the actual service life requires evaluation to the requirements of IEC 60601-1:2005.

Caution: Precautions prior to use.

- □ When turning on the SGU, ensure all LEDs illuminate during the Power On Self Test and no error messages are displayed, else refer to Troubleshooting section below.
- ☐ Ensure that all cables are properly installed and secured.
- □ Ensure that the mains power supply is isolated and that attached equipment is also electrically isolated and does not pose an electrical hazard.
- ☐ If the Stimulator has been unused or may have been disconnected from mains power supply for more than 1 month, charge backup battery by leaving connected to the mains supply in Standby Mode overnight.
- Do not use the Stimulator if any component appears damaged, computer appears to start up abnormally, or error messages appear on the computer screen or Stimulator front panel. If in doubt, contact the Distributor or Micropace directly.
- Ensure that the Operator is trained thoroughly on how to switch the Stimulator to Backup Manual mode or Emergency Fixed Rate Pacing modes.
- To prevent custom software malfunction, do not install other software.

Caution: Precautions during use.

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- Observe the Stimulator and patients at all times for abnormal function and rectify any problem promptly or disconnect the patient from the Stimulator (by unplugging the green plug from the green PACE OUTPUT socket on the front panel).
- □ Do not use the Stimulator and disconnect it from the patient if it repeatedly switches to Backup Manual mode and displays error messages on the front panel. Contact your Micropace Distributor.
- Use of excessive stimulation currents may induce fibrillation and produce misleading results in ventricular stimulation studies.

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2 DEVICE RATINGS, CLASSIFICATION AND CERTIFICATION

CE Mark Compliance

The Micropace Cardiac Stimulator, is compliant with the following EEC directives:

- □ 89/336/EEC & 92/31/EEC (EMC Directives)
- □ 93/42/EEC & 2007/47/EEC (Medical Device Directive)
- □ 93/68/EEC (CE Marking Directive)



Compliance Testing was carried out and coordinated by the following certified bodies:

- EMC Technologies, Castle Hill, Australia
- □ TCA Testing and Certification Australia, Chatswood, Australia

The Micropace Cardiac Stimulator classification:

- □ TGA, Rule 4.3 Classification Class IIb
- Medical Devices Directives (93/42/EEC, 2007/47/EEC & 93/68/EEC), Rule 10 classification: Class IIb medical device
- □ IEC60601-1 electrical device classification:

 Class II (mains-isolated by approved external isolation transformer), IPX0, Type CF
- FDA Medical Device Level of Concern Level II
- Health Canada Medical Device Classification, Rule 10(2)
 Class III

The Micropace Cardiac Stimulator system Power rating:

□ 220-240VAC 50-60Hz, 0.7A max / 110-120VAC 60Hz, 1.4A max

Identification of technical standards with which compliance is claimed

- □ ISO 13485 Quality management systems Medical devices System requirements for regulatory purposes
- □ IEC60601-1:2005 Medical Equipment Part 1: General requirements for safety.
- □ IEC60601-1-2:2007 Medical Equipment Part 1: General requirements for safety. Collateral Standard: Electromagnetic compatibility Requirements and tests

Environmental Conditions

□ Operating T° Range +5°C to +35°C (30% to 80% RH)

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3 COPYRIGHT, WARRANTY AND DISCLAIMER NOTICE

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4 EXPLANATION OF SYMBOLS

Symbol	Name	Meaning	Location
€	Follow Instruction for Use	Follow Instruction for Use	On Stimulus Multiplexer Box (MP3086) and Stimulus Generator Unit (MP3008)
(B	Read Instruction for Use	Read Instruction for Use	On product label
Contents :1	Contents	Contents.	On shipping label.
E	Component of	This is a component of a system.	On product label.
ا لم	Manufactured on	Manufactured on date: YYYY-MM.	On medical device product label.
	Manufactured by	Legal Manufacturer	On medical device product label.
1	Type CF Defibrillator Proof	Type CF defibrillator protected equipment (Protected against intra-cardiac voltages during external defibrillation).	On Stimulus Generator Unit, MP3008: 1. Pace Output Socket. 2. Emergency Fixed Rate Pacing output socket.
	Patient Outputs	Stimulus outputs connect to patient box or SM Box here.	As above.
	Warning	Cardiac pacing output. Read Important Patient Safety Warnings and General Precautions in Handling Stimulator section at the front of this document.	As above.

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Symbol	Name	Meaning	Location
♠	Attention	Electrocution Hazard,ensure that Isolation Transformer has Mains Cord Retaining Bracket MP3181 installed at all times."	Isolation Transformer.
	Attention	Connect only to Micropace supplied parts.	AUXILIARY PORT on MP3008.
WARNING	Warning	Not Suitable for direct connection to RF Ablation Power > 150W into 300 Ohms.	On MP3086 and MP3014.
C € 2797	CE Marking & Notified Body Identification	Complies with European Medical Devices Directive (MDD).	On MP3008.
C€	CE Marking	Complies with EMC and Safety Standards for distribution in Europe.	Accessories. 1 Isolation Transformer. 2 Low voltage Transformer.
\triangle	Equipoten- tiality	System central grounding terminal.	Isolation Transformer.
0	Power OFF	Device is switched OFF; battery is NOT charging.	POWER ON/OFF switch of MP3008.
I	Power ON	Device is switched ON and battery is charging.	POWER ON/OFF switch of MP3008.
	Increase / Decrease	Increase / Decrease adjacent Interval or Current parameter.	On the front of MP3008 next to Interval Current displays.
+	Positive Output	Positive stimulus output. Defibrillator CF Protected part.	On MP3014 and MP3086.
	Negative Output	Negative stimulus output, Defibrillator CF Protected part.	On MP3014 and MP3086.
O Fault	FAULT	Fault Detected in Stimulus Multiplexer Box – use Emergency Bypass.	On MP3086.

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Symbol	Name	Meaning	Location
Emergency Bypass Ch2 - Ventricle	Emergen-cy Bypass	Emergency Bypass output socket - pace Ch2 (Ventric), or use Emergency Pacing on the Stimulator.	On MP3086.
MicroPace	Backup Stimulator Here	Sign indicating location of Stimulator SGU MP3008 for backup pacing.	Next to where SGU MP3008 is installed.

Table 1 Explanation of symbols

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Table 2 below lists explanations of symbols displayed only on the SGU MP3008

Symbol	Name	Meaning	Location
		No light: No external power.	
_		Orange Light: Connected to Mains Power, SGU Off, Battery is not charging.	
-=	Mains Power	Green Light: Connected to Mains Power and SGU on – in Manual Backup or PC Pace Control modes. Battery is charging.	
		Green Light Flashing: Connected to Mains Power and SGU in Standby. Battery is charging.	Left Front Panel of Stimulus
${}^{(\!$	Battery Power	SGU is powered by Battery.	Generator Unit.
	Battery Low	Battery is nearly discharged. Connect to mains power to continue use of SGU.	
	PC Pace Control	SGU is under control of Computer.	
	Backup Pace	Backup / Manual pacing controls are located here. This can be used to pace when not under control of the computer.	
▶ /■	Pace On/Off	Press to start / stop pacing.	Left centre Front Panel of Stimulus
	Backup / Standby	Press to toggle between Backup Manual Pace Control and Standby.	Generator Unit.
ms	Pace Interval	Basic pacing interval in ms.	
‡_ L m	Current	Current amplitude of stimulus.	
\rightarrow III	Pace Output	Stimulus output and indicator lights are here.	Right centre Front Panel of Stimulus
[F	Ch1 (Atrium)	Green flash: Stimulus into Channel 1, usually located in Atrium.	Generator Unit

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			1	
IÆ	Ch2 (Ventric)	Green flash: Stimulus into Channel 2, usually located in Ventricle.		
Ж	Check Lead	Stimulus current not able to be delivered because of a break in the electrical lead / circuit.		
\rightarrow \blacksquare	Emergenc y Fixed Pace Output	Plug green patient connection cable into this socket to immediately pace Ventricle Ch2 at 100ppm @ 5mA. Note: Ch1 Atrium is not paced.		
_ R →∏ 600 <u>I∏ 5</u> .om	Pace V at 100ppm @ 5mA	As above.	Right Front Panel of Stimulus	
1€	Pace V Ch2	Green flash: Stimulus on Channel 2, usually located in Ventricle.	Generator Unit	
${}^{\!$	Battery	Emergency Fixed Pace Output enabled and powered from a battery with adequate charge.		
===	DC Power	Direct Current power input, voltage and current consumption as specified.		
	Computer Link Port	Port for connection to controller computer, use only Micropace supplied cables.		
•	Auxiliary Port	Port for connection to Stimulus Multiplexer Box, use only Micropace supplied cables.	Rear panel of Stimulus Generator Unit	
↓	ECG-1 Input ECG-2 Input	High Level ECG input, 1V peak-to-peak.		
	Sync-1 Output	Digital 0-5V sync output for triggering recorders		
C	Replace	Replace battery on specified date with specified batteries.	Battery Replacement	
4	Battery	Contains Batteries	Label on SGU	

Table 2 Explanation of symbols – specific to the SGU.

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5 EPS320 Family of Cardiac Stimulators



Figure 1: EPS320B/T, StimCor™ and StimLab™

5.1 Description of Stimulator Family

The EPS320 Cardiac Stimulator is a diagnostic external programmable cardiac stimulator.

The Cardiac Stimulator consists of a self-contained two channel microcontroller-based Stimulus Generator Unit, MP3008, capable of generating simple regular pacing pulses by the controls on its front panel. During normal use, however, it is externally programmable by using a computer to generate complex pacing patterns.

The two stimulation channels are independent isolated current pulse generators capable of generating 0.5 to 10ms pulses at 0.1 to 25mA with a maximum output voltage of 27V. The stimulus output may be used to stimulate the human heart during electrophysiological studies via any third party legally marketed transvenous intracardiac pacing catheters. These may be connected directly or via any third party legally marketed EP recording equipment intended to switch pacing pulses of above description to selected specific catheters and electrodes.

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6 EPS320B/BT CONFIGURATION

6.1 Description of system

The Micropace EPS320B/BT EP Stimulator System is a computerized Cardiac EP diagnostic stimulator system.

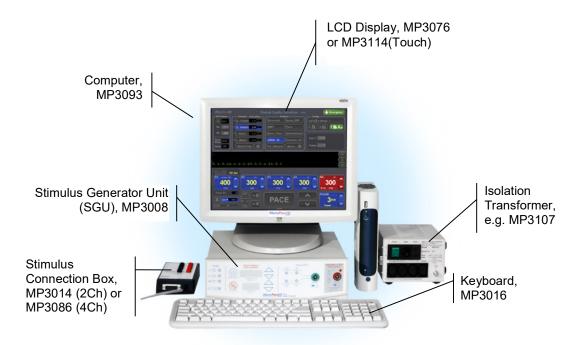
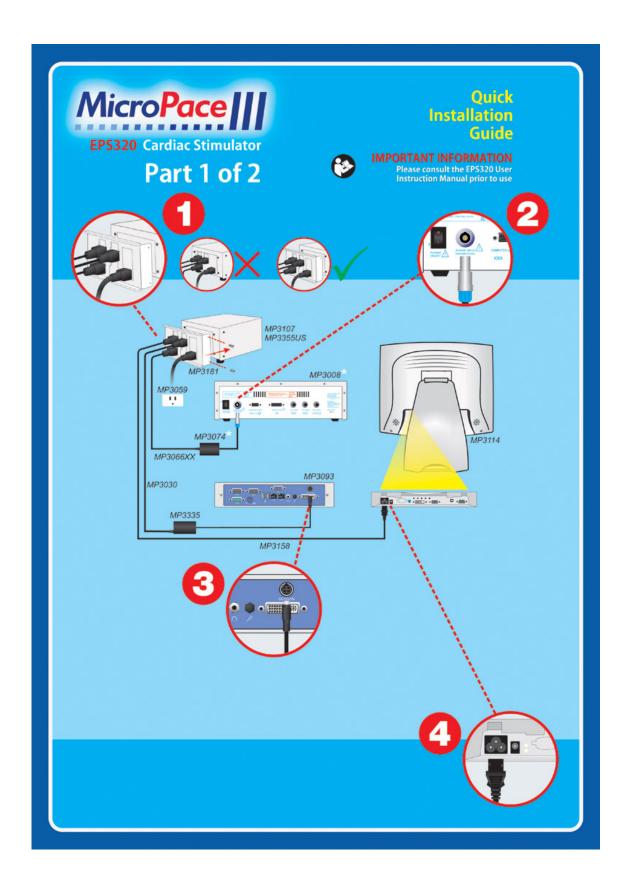


Figure 2 EPS320BT System Components

6.2 System Components

This configuration includes a Bona Computech Light System PC, a separate NEC LCD Display Screen and a 110-240VAC Mains isolation transformer with the EPS320 system. Appropriate mains cables are included for proper system installation, as per Packing list below.

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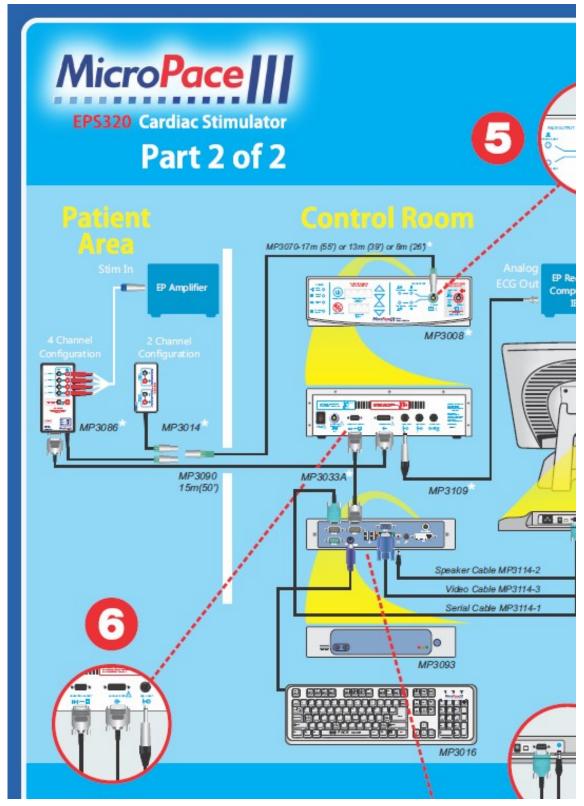


Figure 3 EPS320BT Quick Installation Guide

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6.3 EPS320B/BT Optional Installation Accessories

Part Number	Name	Description
MP3114 MP3113 (kit)	Touch Screen Kit	ELO Entuitive Touch LCD Screen
MP3086 MP3091 (kit)	Four Channel Multiplexer Kit	Alternative PC-controlled Stimulus Connection Box with four Stimulus Channel Outputs 1-4
MP3096 (kit)	StimLinkTM Kit for communication with EP Recorder.	Opto-isolated outgoing RS232 communication channel for connection with EP Recorder with corresponding Software receiver.
MP3070-XX XX = 08 XX = 13 XX = 17	Extension Stim Cable Kit – For Stimulus Connection Box in variants: 8M, 13M & 17M	Low capacitance extension stimulus connection cable.
MP3090	Extension Stimulus Multiplexer cable, 15m	Extended control cable for four channel stimulus multiplexer – MP3086.
MP3084-12 MP3084-25	Extension Serial RS232 Cable, (incl. RF suppression) – 12m or 25m	Standard extension RS232 connection cable for connection between SGU and PC.

Table 3 List of available Installation Accessories for the EPS320B/BT Cardiac Stimulator.

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7 STIMCOR™ CONFIGURATION

7.1 Description of system

The Micropace StimCor™ EP Stimulator System is a computerized Cardiac EP diagnostic stimulator system with a new integrated hardware to support "Cockpit" laboratories and a remote monitor.

7.2 How Supplied

Main Components of the StimCor™ system comprise of the EPS320 Stimulus Generator Unit (SGU), the Computer Cabinet and the Local Controller.



Figure 4 StimCor™ System Components

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7.3 System Components



Figure 5 StimCor Quick Installation Guide

7.4 StimCor™ Optional Installation Accessories

Same as EPS320B/BT.

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8 STIMLAB™ CONFIGURATION

8.1 Description of system

The Micropace StimLab™ EP Stimulator System is a computerized Cardiac EP diagnostic stimulator system based on the EPS320 Cardiac Stimulator with a new hardware platform to support a remote bedside slave monitor and controller located up to 17m from the central installation. The remote bedside controller displays all Stimulator settings and allows their supervision and adjustment if necessary by the scrubbed physician.

8.2 How Supplied

Main Components of the StimLab™ system comprise of the EPS320 Stimulus Generator Unit (SGU), the Computer Cabinet, the Local and the Remote Bedside Controllers.

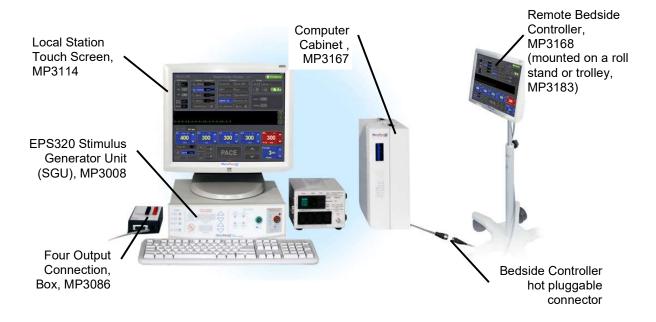


Figure 6 StimLab™ System Components

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8.3 System Components

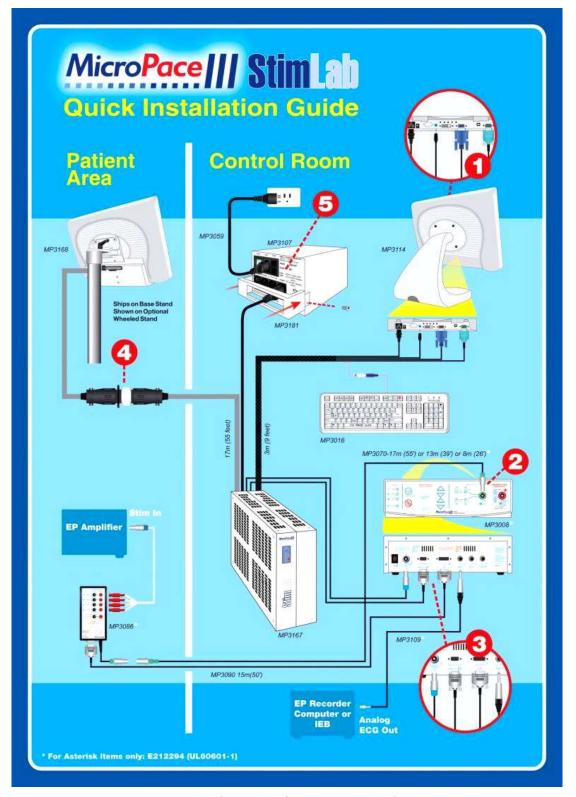


Figure 7 Stimlab™. Quick Installation Guide

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8.4 StimLab™ Optional Installation Accessories

The following optional Installation accessories are available from Micropace for the StimLab™ System.

Part Number	Name	Description
MP3096 (kit)	StimLink™ Kit for communication with EP Recorder.	Opto-isolated outgoing RS232 communication channel for connection with EP Recorder with corresponding Software receiver.
MP3084-12 MP3084-25	Extension Serial RS232 Cable, (incl. RF suppression) – 12m or 25m	Standard extension RS232 connection cable for connection between SGU and PC.
MP3183	StimLab™ Mobile Stand	Five wheeled variable adjustment stand for Remote Touch Screen.

Table 4 List of available Installation Options for the StimLab™ Cardiac Stimulator System.

9 INSTALLATION

Refer to the Micropace EPS320 Family Technical Description for full installation instructions.

Installation is to be performed by Qualified personnel only, such as your Distributor or Authorized Micropace representative.

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10 Using the Micropace Cardiac Stimulators

10.1 Connecting the Stimulus Connection Box

Connect the Stimulus Connection Box, MP3014 to the green PACE OUTPUT socket on the front panel of the Stimulus Generator Unit. The EP Recording Equipment's stimulus input cable(s) connect to this connection box via shrouded 2mm connectors.

Do not connect any plug into the red EMERGENCY FIXED RATE PACING OUTPUT except in case of Stimulus Generator Unit failure when emergency pacing is required.

Connect External ECG Inputs – Most modern EP Recording systems have only one high level ECG output, connect this signal to the ECG1-INPUT with ECG cables provided (MP3034 or MP3109); you will see this ECG from the EPS320 software as the ext-ecg1 accessed with the ALT-1 hotkey. You will then have to select required ECG sensing source on the EP Recorder.

10.2 Switching on the system

Switch on the computer, the LCD screen and the Stimulus Generator Unit.

10.3Using the computer

The Micropace Cardiac Stimulator system comes with a Bona Light System PC. The front panel of the computer is shown in

Figure 8





Figure 8 Computer front panel for EPS320B/BT (left) and StimLab / StimCor (right)

FEATURE	Explanation
1. USB Port:	For Micropace Configuration Management Tool only. Do not connect non-Micropace USB devices.
2. Microphone In:	Do not use.
3. Line Out:	Connection for MP3113 touch screen audio Input. Use Line out on rear of PC.
4. LAN LED:	Not Used
5. HDD LED:	Not Used
6. Power LED:	Indicates computer is switched on
7. Power Switch:	Push On/Off

Table 5 Computer Front Panel Explanations

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10.4 Setting up the computer

- a. Switch on (i) Isolation transformer, (ii) Bona PC (push front button once), (iii) LCD Display (on the side) and (iv) SGU at the rear. Allow system to boot up.
- b. When prompted respond that you are the distributor (to avoid having the License agreement shown to you)
- c. If you have an EU version, you will be offered a menu to chose an interface language.
- d. When prompted to calibrate screen, touch screen in the places indicated by crosses from the seated position and the same eye level as the customer will use, using the stylus. Calibration of each touch screen must be performed.
- e. You will now see the Main Stimulator Screen.
- f. The Stimulator software will already be configured for your hardware setup touch screen, four channels and one external ECG

10.5 Indicating location of SGU

Where the SGU, MP3008, is located out of sight of the operator's normal position, apply label MC0809 "Backup Stimulator Here" to make SGU's location clearly visible to the operator during normal use.

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11 Using the Keyboard and the Touch Display

The Stimulator may be operated by keyboard alphanumeric hot keys indicated in software menus and on key labels, Figure 9 shows the main hot keys.

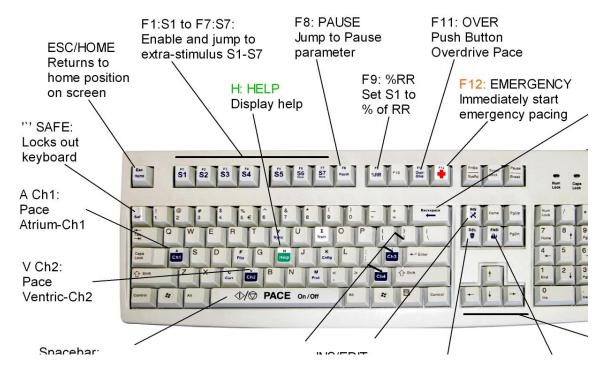


Figure 9 Keyboard Layout

The Touch Screen is a 15" touch LCD display

- You may use your finger, gloved finger or a soft stylus, such as the back of a plastic pen.
- ☐ The user may focus screen parameters by touching them and then modify their values with the + / buttons on the screen. This includes S1 to S6 and all menus in the upper half of the screen.
- Numerical entry may be by a numeric keypad opened either by the NumPad touch button or by double tapping the parameter.
- Press and hold the purple Emergency
 Pace button for instant pacing at any time.
- □ Press 'ALT Menu' to display more, alternate menus.
- Press Enter button on the screen when displayed to enter values or exit menus.
- □ Press on Exit Icon ('X' in a box) to exit menus.



Figure 10 Touch Screen

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Touch buttons; their keyboard equivalents and their functions are described in the table below.

Touch Button / Zone	Keyboard hot key	Function
Any menu item	Highlighted underlined, usually first letter of name	Selects and makes active the menu item.
PACE	Spacebar	Toggles Pacing On/Off, sustained touch – push to pace.
	INS / EDIT	Enables Sx, edits focused parameters
Del W	DEL	Disables Sx, modifies focused parameters
	+/-	Small Increment / decrement, e.g. S1 by 10ms
♣ Emergency	F12- Emergency	Starts emergency pacing into both channels. Prolonged press of 0.35 sec required to activate.
×	Q / Esc	Exits menu / application
<u>→</u>	Alt-Q	Press the button showing the QRS signal and the QRS Detect Window will appear. The up & down arrows above and below the QRS button will adjust the Min Threshold value +/-
(F9 90%RR)	90% (F9)	Make S1 90% of average RR, or whatever value programmed. The Percent value now adjustable by Config Var 9 'F9 %RR Percentage'
Overdrive 380 Ch2	F11	One touch Overdrive Burst Pace. Prolonged press of 0.35 sec required to start pacing 1st time and again whenever button left idle for 20 sec; button remains green color when armed for immediate pacing. "Ch2" indicates which channel will be paced and 380 indicates the set S1 interval. Slide finger while pacing to the right towards '-' symbol to reduce S1 interval while pacing, or to the left to increase S1.
Input: Touch	None	Toggles control between Keyboard only, Touch only and Both
ΛΩ V Σ 0	None	Measured Pacing Results Ω: Pacing Impedance in Ohms V: Pacing Voltage in Volts Σ: Number of pacing stimuli generated

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Touch Button / Zone	Keyboard hot key	Function
AltS 💾	Alt-S/Alt-R	Save / Restore settings
K R	К	Configure Stimulator
(HB)	Н	Help
E A /B	F	Flip / change between Stimulator Page A and Page B
RR:	None	R-R Interval in ms
HR:	None	Heart Rate in beats per minute
Sync Mode: 1stS1	Υ	Synchronize pacing to ECG
Delay: =S1	None	Delay from Sync to S1
<u>D</u> ecr ▼	D	Decrements S values
Train S1:	1	Set number of pacing stimuli in one Train
★ mA	Ctrl-Ins/ Ctrl-Del	Maximum Current
S	None	Stimulation delivered
ALT CTRL SHFT	Alt / Ctrl / Shift	Key pressed

Table 6 Touch buttons, touch zones and their functions

11.1.1 Numeric Keypad

The custom designed Micropace Compact Numeric Keypad Kit (MP3393) with a specially modified key layout and can be connected to the system to replace the Standard Keyboard and reduce desktop clutter. It should only be used with systems having a touch screen and Software version 3.21 or higher. Follow all Instructions for Use provided with the Compact Numeric Keypad when installing and using it.

Caution: standard numeric keypads must not be used with the EPS320 Family of Stimulators as they will not function as expected.

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11.2 Using the StimLab™ Bedside Controller Features

Micropace bedside controller may be wheeled into the EP lab and hot-plugged to the Stimulator in using the Quick Connector, ready for use.



11.2.1 Input Device Control



Pressing the Input button in right lower corner of display opens the Input Selection Menu which allows the user to selectively enable the Local Touch screen, the Remote Touch screen and the Keyboard.

Once Selected, the Input parameter then indicates the selected combination of input devices with "LT". "RT", "KB" and "All".

11.2.2 Local/Remote Indicator:

This text indicator at the top of the PACE button indicates which Station is currently in use and thus has exclusive control:

- (i) "Local"
- Local screen is in exclusive control (keyboard is also pressed)
- (ii) "Remote"
- Remote screen has control
- (iii) " "
- No text when neither screen touched for > 2 seconds



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12 Using the Stimulator Software

12.1 Help Function

Help is available for every parameter and every protocol when focused by pressing the 'H' hotkey

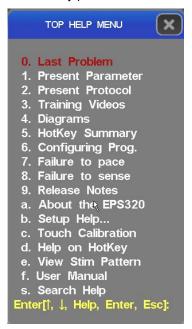


Figure 11 Help menu

12.2 Training Videos

Training videos are available from help menu item "3. Training Videos". Use touch to select topics.

12.3 Help Search

The help system has a search facility accessed from menu item "s. Search Help".

12.4 The Main Stimulator Screen

The main screen will appear with the PACE protocol selected as shown in Figure 12. The red focus highlight will be on the S1 parameter allowing the Operator to adjust the basic pacing interval with the numeric keys or +/- keys. The focus is moved around the screen with arrow keys.

12.5 Pacing Parameters

To set the parameters in Figure 12, first press the hotkey indicated by the underlined letter in the parameter's name to focus on it and then use the numeric keypad '+'/'-' keys to adjust the parameter or enter a new value using the numerical keys.

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12.6 Basic Pacing

To toggle pacing on or off, briefly tap the PACE key (Spacebar) or Touch Button; sustained press of PACE causes pacing only while PACE is pressed.



Figure 12 Stimulator User Interface screen set to PACE protocol.

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Using the Stimulator Software Protocols *12.7*

Threshold Protocol. Press 'T' to select the THRESHOLD protocol. Next, start pacing by pressing the [Spacebar]; output current will be automatically decremented. You will need to stop pacing when loss of capture occurs.

ECG Display Bar. During pacing, the ECG Display Bar in the screen centre will draw vertical Stimulus Symbols for each stimulus in each output channel (short vertical lines for S1, taller for S2-S7, 'L' shaped if high impedance)...

Nodal ERP and Multi SX Protocols. The NODAL ERP protocol features 3 extra-stimuli for refractory measurements, with adaptive autodecrementation by 50's and then by 20's or 10's. The MULTI SX protocol provides up to 6 extra-stimuli for programmed ventricular stimulation also with individually controled decrementation.

Wenckebach, Burst Pace Protocols. The WENCKEBACH protocol continuously decrements S1 (paused

by continuous press of the

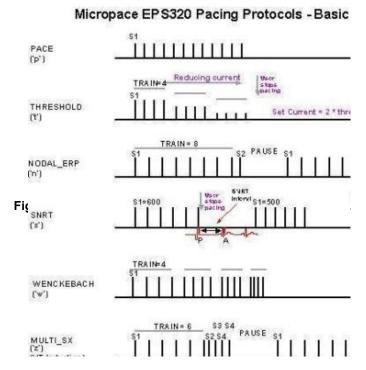
[Spacebar]). BURST PACE protocol allows more rapid pacing with S1 values as low as 30 ms (lower limit for S1 in Burst set in the Config Menu, hotkey 'K', Config Var-2). Stimulation patterns for these basic protocols are shown in Figure 13 above.

RSynced Sx, SNRT and AV Delayed Protocols. The Rsynced Sx protocol produces a train of up to 3 extra-stimuli coupled to a train of sensed P/QRS complexes. The SNRT protocol displays an elapsed-seconds allarm timer and automatically decrements S1 after stopping pacing. The S1 adjustments may be programmed by the AUTO DECREMENT variable, which may use a Table of values, accessed by pressing [Ins] with variable focused. The AV_DELAYED protocol provides sequential A-V pacing where S1 is the basic pacing interval and the S2 variable sets the AV-delay.

Overdrive Pace and ATP Protocols. Tachyarrhythmia may be rapidly terminated by the temporary OVERDRIVE BURST PACE protocol, accessed with the hotkey 'O'.

ECG sensing. Stimulator may sense ECG from either of two external high level ECG Inputs (1 volt pp), or may sense intracardiac ECG (IECG) from the pacing electrodes of either channel.

Saving Stimulator Defaults. Stimulus and protocol-related parameters for the currently displayed protocol may be made defaults for that protocol by storing them in the Protocol Setup Memory simply by pressing the hotkey 'Alt-S' and [Enter]. Note that default CURRENT variable is an exception, and can be stored only in the THRESHOLD protocol.



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12.8 Pacing Protocols

The Micropace Stimulator features a number of pre-programmed stimulation protocols.

12.8.1 Protocol Selection & Renaming

Favourite protocols in the Protocol Toolbox ('M' hot key) may be selected with checkbox to appear in main Protocol Menu and may be renamed from a customizable list using the EDIT key.

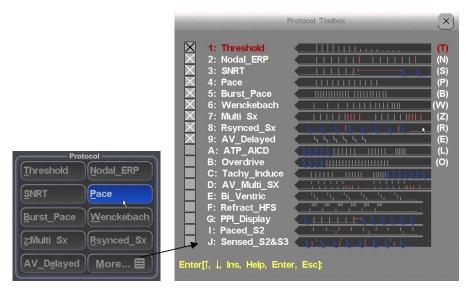


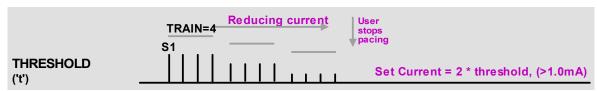
Figure 14 Protocol Toolbox

12.8.2 Pace Protocols



Select the PACE protocol to pace at a fixed interval set by S1 into selected pacing site.

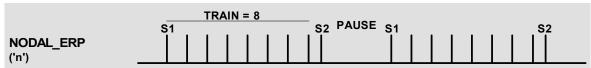
12.8.3 Threshold Protocol



The THRESHOLD protocol helps to determine the pacing threshold by continuously decreasing or increasing the pacing Current amplitude; the Operator needs to stop pacing when capture is lost, and accept or modify a displayed automatically calculated new default current (twice threshold current, and > 1.0 mA).

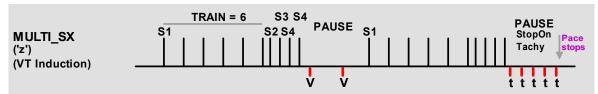
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12.8.4 Nodal_ERP Protocol



The NODAL_ERP study provides up to 3 auto-decremented extra-stimuli for AV Node refractory and other measurements. S2-S4 may be auto-decremented by 50, then 20, then 10ms as Sx value reduces from a Table accessed by Editing Decrement Parameter, or by an arbitrary single value set by Decrement (disable decrementation Table by setting Config Var-11 to 0).

12.8.5 Multi_Sx Protocol



The MULTI_SX protocol provides up to 6 auto-decremented extra-stimuli primarily for programmed ventricular stimulation. A warning message "Defibrillator Ready?" appears on entry to protocol if pacing into Ventricle, its appearance is configurable by your distributor. In both above protocols, manual adjustment of Sx suspends next auto-decrementation and the BSP key reverses last auto-decrement.

SX property menu is opened on selected Sx using Ins/Edit and contains:

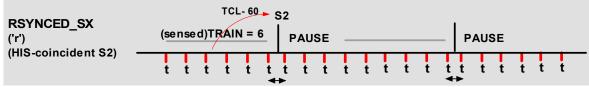
- □ Enable first S1 Trigger from Sensed P/R or no trigger.
- Enable AV delay for S1.
- □ Set S1 AV delay time in ms.
- Set individual S1 Train number control. The train value is displayed on the bottom of the Sx button.
- □ Enable individual S2- S7 auto-decrement for this Sx according to the common decrement value set in the Stimulus Menu.

12.8.6 Wenckebach Protocol



The WENCKEBACH protocol continuously decrements S1. Decrementation may be optionally terminated by manual adjustment of S1 (configurable by your distributor); in software versions 3.19.59 or earlier, decrementation was also paused by continuous press of the [Spacebar].

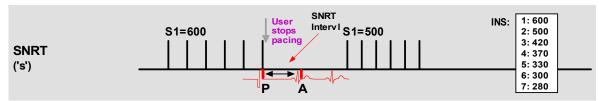
12.8.7 RSynced_Sx Protocol



The RSYNCED_S2 protocol produces a train or a sequence of up to 3 extra-stimuli coupled to a train of sensed P/QRS complexes.

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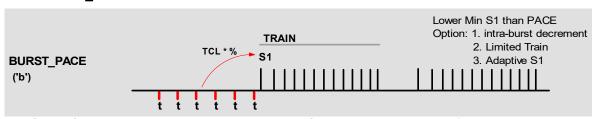
12.8.8 SNRT* Protocol



The SNRT protocol displays an elapsed-seconds alarm timer and automatically decrements S1 after stopping pacing according to a SNRT Table. The SNRT Table is accessed by pressing [INS] when the screen focus is on the AUTO_DECREMENT or S1 parameters while in the SNRT protocol. Alternatively, the AUTO_DECREMENT variable may be used to decrement the S1 (customised by your distributor).

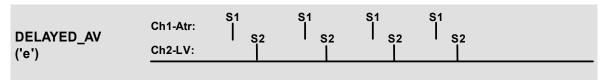
*Note: SNRT value calculation may not function correctly when sensing IECG from the catheter-tip; use external ECG sensing to obtain SNRT calculation by the EPS320 Stimulator.

12.8.9 Burst_Pace Protocol



BURST_PACE protocol allows more rapid pacing with S1 values as low as 30ms (subject to its own Config Var-2 'Lower limit for S1 in Burst'). Configuration Variable 7 can be used to redirect Burst Pace to Overdrive Burst pace whenever burst pace is engaged.

12.8.10 AV Atrio-ventricular Delayed Protocol



The DELAYED_AV protocol provides sequential A-V pacing where S1 is the basic pacing interval and the S2 parameter sets the atrio-ventricular delay.

12.8.11 Overdrive Pace and ATP Protocols



Terminate tachycardia rapidly by jumping to the temporary OVERDRIVE BURST_PACE protocol (hotkey 'O'). The OVERDRIVE pacing site and the final S1 value will be remembered on the next call to the OVERDRIVE protocol. Hotkey F11 allows one push-button overdrive pacing.

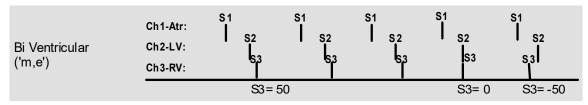
The ATP_AICD – anti-tachycardia pacing, protocol (hotkey 'L') provides overdrive pacing protocols similar to those used in Implantable Defibrillators (AICD's).

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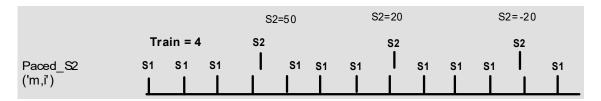
12.8.12 Specialised Protocols

The following specialised protocols are available from the Procedure Menu ('m'). They are self-explanatory.

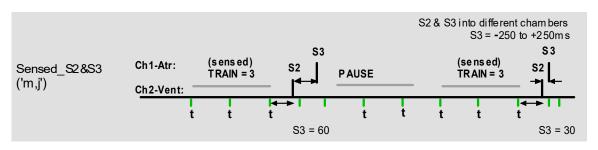
Bi Ventric Pacing. This protocol requires the Four Channel Upgrade, using the Four Channel Multiplexer Kit, MP3091:



Paced S2. S2 into a different channel to S1 is interpolated between S1stimuli. S2 may be 0 or –ve, meaning it coincides or precedes the last S1:

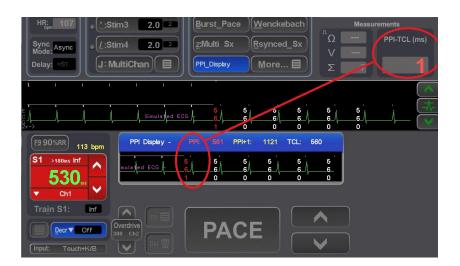


Sensed S2&S3. Multiple sensed extra-stimuli are given into different channels / chambers:

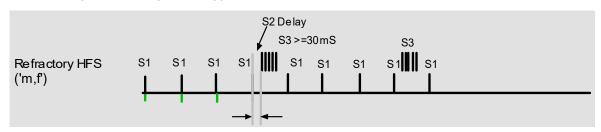


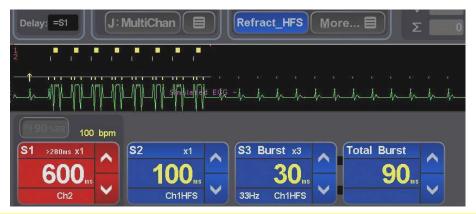
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PPI Protocol. This protocol displays the Post Pacing Interval during entrainment studies of tachyarrhythmias.



Refractory High Frequency Stimulation. Regular S1 into Ch2 with HF burst into Ch1. S2 Delay from S1 to S3. Minimum S3 burst of 30mS.





In the high frequency burst protocol, you may specify a train with a frequency and either as a number of stimuli or a duration of pacing. For example, (S1=40ms, train of 3) or (S1=40ms train for 80ms).

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12.9 Software configuration.

Configuration Menu. Software configuration, including various safety limits and options may be adjusted by the installing technician according to customer preferences using the password protected CONFIG utility, hotkey 'K'.

Storing multiple Protocol Defaults. You may store up to 8 different sets of Protocol Parameter defaults. Store Parameters as above except after pressing 'Alt-S', select one of eight memories. Retrieve a protocol by the 'Alt-R' hotkey, followed by the number of the memory.

12.10 Sound Configuration

The Stimulator system outputs the sounds produced during use (stimulus sound, sensed ECG and others) to external speakers (as well as continuing to make the sound internally in the PC and the SGU).

WARNING:

Any connected amplified speakers must be powered by a medically isolated mains power source, such as the Micropace Isolation Transformer MP3107.

12.11 Safety Features

For urgent pacing, press F12. If Computer fails use Backup Manual Pacing on SGU (Step 3 below); if SGU itself fails, use Emergency Pace (Step 4 below).

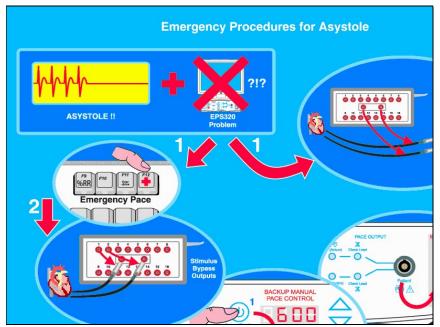


Figure 15 For urgent pacing

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12.12 Software Error Messages

Error messages have help messages associated with them. In some cases help text appears with the error message; with other errors, pressing 'h' displays the associated help text.

Run time timing error

The following message may appear while using the Stimulator.

Internal Error: STIM OVERRUN: The Computer is not keeping up, stimulus timing may be inaccurate!

This can happen if you have continuously pressed a key, forcing the software to service the keyboard too frequently, or there is some problem with the computer. Note that subsequent pacing will most likely be accurate, but this message will come up only once in any one session and any repetition of this error will be ignored for the rest of the session, to enable you to continue pacing the patient if necessary. To re-enable this error detection, quit the program with 'Q' and follow the prompts to restart the software or by rebooting the computer.

Program warnings on exit

The following message may be displayed after exiting the program.

Program exited with Warnings, logged in file 'stim.log'.

This indicates that a warning was issued during execution of the program.

Contact your Distributor for further details if required. Abnormal program exit will also result in the display of a Recovery Menu. Follow the suggested menu items to recover your last valid configuration settings or to re-install the program.

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12.13 Additional Software Messages

12.13.1 Advisory Messages

These short advisory messages are intended to notify user of some abnormal conditions, which however may not need any action or response from the user and thus do not interrupt the user performing the EP study.

They appear in one of four zones below the ECG Display Bar and are displayed only for several seconds.

Hardware related Advisory Messages	Explanation	Suggested Action	
Noisy PC Comm	PC detected sequence error in last RS232 data packet from SGU.	Check, re-insert or replace Serial Boost Cable (MP3033A) between PC and SGU.	
Noisy PC Comm- Hw	PC detected parity/framing/overrun error in last RS232 data packet from SGU.		
Noisy SGU Comm	SGU detected parity error in last RS232 data packet from PC.		
High Atrial Impedance	High impedance on atrial channel - calculated impedance > 4kOhm or current < 75% of programmed current with output voltage on maximum.	Check for cable disconnection, wrong 'Stim setting' on recording equipment and pacing catheter integrity.	
High Ventr Impedance	As above but for Ventricular channel.		
Ext Sync1 Detected	Sync pulse input detected on Ext.Sync1 input port.	Not used. Contact distributor if sign appears.	
Ext Sync2 Detected	Sync pulse input detected on Ext.Sync2 input port.		
Ext Power Disconnected	External 15V power supply is disconnected (or < 2.5VDC). SGU operating on backup battery power.	Reconnect external power.	
Backup Battery Low	Backup battery has low charge.	Connect external power to recharge. If persistent, Backup Battery requires servicing.	
Output Interference	Output current not within +/- 25% tolerance, for either channel.	Ignore if sign related to RF Ablation, else SGU requires service.	
Prog Exception: Internal SGU problem – program flow trap code.		Record code number, disconnect patient from EPS320 Stimulator and request SGU servicing.	

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Software Related Advisory Messages	Explanation	Suggested Action	
Warn: S1< 230ms!	Warns user that pacing has commenced at < 230 ms. Sound alarm associated.	Proceed if pacing at S1 < 230 ms intended.	
Train Done	Informs user that TRAIN number of S1 stimuli has been completed - only in BURST and OVERDRIVE BURST protocols.	Nil required.	
"Waiting for ECG Sync"	Start of pacing pending the arrival of QRS sync from ECG channel. Subject to 'Sync Timeout' below.	If poor QRS sensing, adjust ECG gain or ECG / IECG source for better sensing. Use external ECG for sensing whenever available.	
Sync Timeout!	Sync_To parameter set and pacing commenced but no QRS detected for > Sync_Timeout seconds, set by Config Var 8.	Nil required.	
[INS] sets S1	Reminder message on entry to SNRT protocol that user may access SRNT table by pressing INS key.	Press INS if wish to adjust table of SNRT S1 values.	
Ectopic->Trigg	When 'Prematures Detect' is enabled, notifies user that an Output Sync (trigger) pulse has been sent in response to an Ectopic beat.	Nil required.	
EB,[Esc]toTrigg	When 'Prematures Detect' is enabled and set to Single trigger only, this message appears with the 2 nd and subsequent detected ectopics not causing a Sync Output to remind user that pressing Esc re-arms the Sync Output.	Nil required.	
Use ESC	User using wrong keys to try to exit - needs to use Esc key the displayed menu.	Press ESC key.	
Stuck key	Same key pressed more than 30 times in rapid succession - i.e. pressed continuously.	Release key or service keyboard if faulty.	
Burst Key Lock!	Key pressed while Burst pacing at S1< 100 ms. Must stop pacing to change parameters. After three consecutive key strikes, a text message appears instead.	Stop pacing to change parameter.	
Upper RR Limit: xxx	In Rsynced_SX protocol, [RR interval less His_Coincident_S2] exceeds a pre-set maximum xxx (typ 1060ms).	If under-sensing SVT, adjust ECG source to improve QRS detection.	
S2 = RR – xxx	In Rsynced_SX protocol, indicates calculated S2 value.	Nil required.	
90% RR = xxx	Displayed when F9 pressed, indicating calculation of S1 as 90% of measured RR interval.	Use calculated interval if correct.	
Invalid RR	Appears in Burst, Overdrive, Rsynced_SX protocol when measured RR interval outside of valid range – usually due to under or over-sensing.	Correct ECG sensing.	

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Software Related Advisory Messages	Explanation	Suggested Action
xxx % RR = xxx	In Burst and Overdrive protocols indicates calculation of S1 as a percentage of measured RR intervals.	Use calculated interval if correct.
Lower Limit xxx	Attempt to set S1, Decrement or Train parameter BELOW limit set in Configuration Menu.	Enter new value within limits.
Upper Limit xxx	Attempt to set S1, Decrement or Train parameter ABOVE limit set in Configuration Menu.	Enter new value within limits.
Timing Error	Inaccuracy in verification between PC and SGU clocks.	Stimulus timing may be incorrect – verify stimulation timing with third party equipment. Service the Micropace Stimulator system.
Unstable RR	RR interval not stable during adaptive calculation of S1 interval in ATP protocol.	Check & improve ECG signal / QRS detection.
Output Interference	Outputted current out of tolerance of 25% for either channel; may be due to RF Energy interference on output.	Remove interference; if persists, service SGU.

Table 7 Advisory Messages and suggested actions.

12.13.2 Text Messages

Advisory Notes (NOTE)	☐ These messages inform user of required instructions or information data and are self-explanatory	ve
	They represent either normal or correctable abnormal run-time program conditions.	
	☐ They require a user response and do not terminate the program.	
Run Time Warnings (WARNING)	 These messages warn user of possibly incorrect or inappropriate actions by him. 	
	They require user action or confirmation of an action and do not terminate the program.	
Data Error Messages (DATA_ERR)		
File Error Message (FILE_ERR)	□ Significant errors found, stop using the Stimulator and contact you	ur
Run Time Error Messages (RUN_ERR)	distributor or Micropace for service.	

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12.14Configuring the Program - the CONFIG menu¹

A number of parameters controlling the program's operation, including safety limits are stored in a configuration file and may be altered by the Micropace authorised representative. Contact Micropace or your representative for further information.

The configuration menu is called up by hotkey 'K'. The parameters are shown in Table 8.

User Configuration password is: "henry" or 4546.

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¹ This is a password protected feature for use only by company representative for customisation of program to individual site preferences during installation.

```
USER - Configuration
+---- EPS320 Ver:4.0
                                                                                          Protocol: Pace ----+
>>PGDN/Enter->Service Page 1
1 Minimum S1 for PACE 2
2 Absolute Min S1,eg BURST:
3 Minimum Sx (S2-S7) 4
4 Min.auto S1 for ATP 5
5 Min.auto S1 WENCKE/SNRT 6
6 Min.auto S1 for BURST 7
7 Burst -> Overdrive Burst:
8 Sound Output Source 9
9 F9 %RR Percentage 10 Synclout on (Train+1-n)S1:
11 Decr/Incr N'ERP by Table:
12 W'ke/Brst Autodec'Period:
13 SNRT Auto Stop 14 SNRT Duration 15 Repeats Multi Sx Extra's:
16 En Wencke Log Decrement:
17 En Wencke Beat Decrement:
18 Rate-adaptive Burst S1 19 ATP Intraburst Decrement:
                                                                   21 Min.auto Sx for RSync Sx: 22 Tachy Detect Interval: 23 His-coincident RSynced Sx:
                                                          {\rm ms}^{\,{\rm s}}
                                                          ms³
                                                                                                                             ms
                                                          ms<sup>3</sup>
                                                          ms<sup>3</sup>
                                                                   25 Temp Prot.Boosted Current:
26 ECG gain Atrial Chan
27 ECG gain Ventric Chan
                                                          ms³
                                                                   27 ECG gain Ventric Chan

28 ECG gain Ext1

29 ECG gain Ext2

30 Soft QRS Detect Setup

31 QRS Blanking Time-HWare

32 QRS Sync Timeout

33

34 No of Hints (13,0=off)
                                                          - 3
                                                          _ 3
                                                           _ 3
                                                                                                                             ms
                                                        ms³
                                                                  35
36 Idle Safety Timeout : 37 Sense Sound : 38 Pace Sound Duration : 39 Default Setup No.(1-8) : 40 Set Global FACTORY PRESET: 41 Initial Input Method :
                                                                                                                               S
                                                                                                                             ms
                                                          응 3
 20 Touch Scrolling of Menu: 3
1. Minimum S1 for Pace ......... - Minimum allowed S1 value during non-burst, e.g. Pace protocols.
2. Absolute Min S1,eg Burst ..... - Minimum allowed S1 value during Burst, Overdrive Pace, ATP protocols.
3. Minimum Sx (S2-S7) ..... - Minimum allowed S2 to S7 value.
4. Min.auto S1 for ATP ....... - Min. allowed S1 value reached by auto-decrementation in ATP Protocol.
5. Min.auto S1 WENCKE/SNRT- Min. allowed S1 value reached by auto-decrementation in Wenckebach & SNRT Prot.
6. Min.auto S1 for Burst...... - Min. allowed S1 value reached by auto-decrementation in Burst protocol.
7. Burst -> Overdrive Burst.....- Redirect Burst protocol to Overdrive protocol 0= No 1= redirection
8. Sound Output Source ....... - Sound source; 0=none, 1=PC speaker only, 2=External speaker, 3=Both
9. F9 %RR Percentage..... - Sets F9 – S1 = %RR percentage; range 50% to 99%.
10. Sync1out (Train+1-n)S1 ..... - Send Sync pulse on (drive train+1-value) for triggering recorder, (1=last train pulse).
11. Decr/Incr N'ERP by Table... - Decr/Increment in Nodal ERP is from Table of values - use INS on parameter
12. W'ke/Brst autodec'Period ... - Interval between auto-decrementation of S1 in Wencke and Burst Pace protocols.
13. SNRT Auto Stop ...... - Pacing stops at end of SNRT timer expiry.
14. SNRT Duration ...... - Time to alarm in each SNRT pacing train.
15. Repeats MULTI SX Extra's - Repeat VT extra's before decrementing. NB value 2 => 3 repeated trains.
16. En Wencke log Decremt'n .. - S1 is Auto decremented logarithmically during Wenckebach, i.e. in diminishing steps.
17. En Wencke Beat Decrement - Wenckebach auto-decrementation occurs on every 'TRAIN' no. of stimuli, not time.
18. Rate-adaptive Burst S1 ...... - Initial S1 in Burst & Overdrive protocol will be thus % of RR interval; 0=disabled.
19. ATP Intraburst Decrement .. - Intra-burst reduction in S1 value, i.e. scanning.
20. Touch Scrolling of Menus ... - Allows sliding of finger on menus..
21. Min.auto Sx for RSync_Sx.. - Minimum automatically decremented Sx value for RSynced_SX protocol.
22. Tachy Detect Interval ...... - Sets default tachycardia detect interval for StopOnTachy Pause mode.
23. His-coincident RSynced Sx - Sets nominal HV interval for calculating His-coincident S2 (RR-HV).
24
25. Temp Prot.Boosted Current - Pacing current is boosted by this amount (as mA or %).
26. ECG gain Atrial Chan ....... - Gain for Atrial catheter tip ECG, 1= smallest gain, 4=largest.
27. ECG gain Ventric Chan ..... - Gain for Ventricular catheter tip ECG, 1= smallest gain, 4=largest.
28. ECG gain Ext1...... - Gain for External amplified ECG, 1= smallest gain, 2=largest.
29. ECG gain Ext2...... - Gain for External amplified ECG, 1= smallest gain, 2=largest.
30. Soft QRS Detect Setup ... - Default setup for QRS Detect Menu.
31. QRS Blanking Time-HWare - Minimum Hardware RR detector blanking time – used only if Var 30 is '0'.
32. QRS Sync timeout...... - If no QRS detected by time out, pacing triggered anyway.
33.
34. No of Hints (14,0=off) ...... - Number of Hints on program launch, 0= disable.
35.
36. Idle safety timeout ...... - Idle keyboard for this time triggers safety standby requiring pressing ESC to cont.

    Sense sound ...... - Duration of sound made with each QRS sense. (surrogate for loudness).

38. Pace sound Duration ......... - Duration of sound made with each stimulus by PC and SGU (surrogate for loudness).
39. Default Setup No.(1-5)..... - Setup loaded on program launch.
40. Set Global Factory Preset... - Resets all program parameters to Factory presets.
41. Initial Input Method......- Input device; 1=Both, 2= Touch screen only, 3= Keyboard only.
Note: Press 'h' to obtain further, more detailed help for any variable under the cursor.
```

Table 8 Configuration Menu Page

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13 THE EPS320 STIMULUS GENERATOR UNIT

The Stimlab™ system uses the EPS320 Stimulus Generator Unit (SGU) for generation of cardiac stimuli. The EPS320 has two independent opto-isolated stimulation channels.

13.1 EPS320 Stimulus Generator Unit layout

The front panel, shown in Figure 16 has four sections described below from left to right:

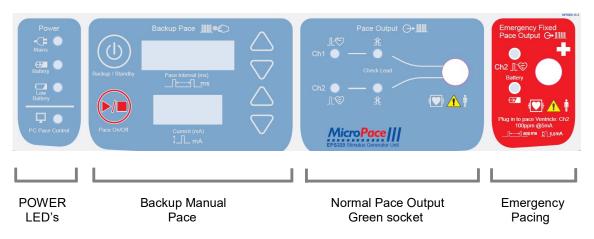


Figure 16 The EPS320 Stimulus Generator Unit front panel

Four power indicator lights on the extreme left:

- (i) Mains Power (green/yellow)
 - GREEN ON mains power is connected and unit switched On at the POWER switch, backup battery is trickle changing, Stimulus Generator Unit is in PC CONTROL or BACKUP MANUAL operation mode.
 - GREEN BLINKING- mains power is connected, unit in STANDBY mode; backup battery charging.
 - □ YELLOW Mains power available, but unit switched OFF; backup battery not charging.
- (ii) Battery Power (orange) mains power lost, operating on backup battery. A minimum of 2 hours of operation is expected from a fully charged backup battery.
- (iii) Battery Low (red) battery charge low, only approximately 10 minutes of operation remaining.
- (iv) PC Pace Control (green) Serial RS232 data link is functioning and Stimulator is under control of computer.

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Backup Manual Pace Control:

Should the computer fail the Stimulator automatically switches into the Backup Manual Pace mode. Pacing may then be toggled on/off by pressing PACE ON/OFF button. Note that pulse width is fixed at 2ms.

Pace Output:

Two green LED's marked Atrium and Ventricle light briefly when stimulation pulse is generated The two LED's labelled Check Lead, signal a high impedance condition during last stimulus pulse, i.e. programmed current not delivered due to very high impedance. This is usually due to a disconnection in the circuit or a broken cable/connection.

Emergency Fixed Pace Output:

In the unlikely case of the Stimulus Generator Unit itself failing, i.e. the Stimulator does not pace even in the BACKUP MANUAL PACING mode and the patient requires urgent pacing, the Operator may pull out the green plug from the PACE OUTPUT socket and plug it into the red EMERGENCY FIXED PACE OUTPUT socket to the right of the PACE OUTPUT socket. The pacing lead impedance automatically turns on the Emergency Fixed Rate Pacing which immediately starts pacing (ventricle only) at 100bpm, with 5mA current and 2ms duration.

13.2 EPS320 Stimulator Connections

Figure 17 shows the connectors on the rear panel of the Stimulus Generator Unit.

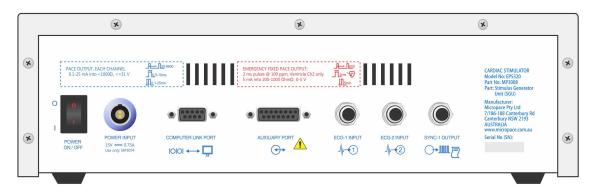


Figure 17 Connectors on rear panel of SGU (reference only)

Power On/Off

This is the main power switch to the Stimulus Generator Unit.

Power Input

External Power input. Connect only to Micropace medical grade power supply, Part No. MP3074. The unit draws average current of 750 mA with a switch on surge of 1.5A at 15 VDC via a Redel 2 pin socket.

Computer Link Port

Serial RS232 data link to computer's COM1 Port; DB9 connector. Use only Micropace Serial RS232 Boost Cable (Part No. MP3033A).

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ECG-1 Input & ECG-2 Input

These are 6.5mm phone jack inputs for high level ECG. Input voltage range is ± 1.0 Volts with an input impedance of 47kOhms, so source impedance should be less than 4.7 K Ω .

Sync-1 Output

This port delivers a CMOS logic (positive 5V) logic 200 ms logical pulse at various times during stimulation.

Auxiliary Port

This port allows connection to Stimulus Multiplexer Box, MP3086.

13.3 Hardware Error Messages on the EPS320 Stimulus Generator Unit

Hardware errors appear on the 7-segment LED displays labelled 'Pace Interval' and 'Current' and indicate operational failures concerning the Stimulus Generator Unit.

Error Message	Error Name	Explanation	Suggested action
C,P,U,_,E,r,r	CPU Error	CPU self test failure.	Contact distributor
P,O,r,,E,r,r	POR Error	Hardware watchdog self test failed	Contact distributor
b,u,t,n,E,r,r	Button Error	One of the front panel buttons/keys are stuck in the ON position.	Contact distributor
S,O,F,t,x,x,x	Software Error	where xxx is any 3-digit number. Software execution miss-flow trap number.	Contact Distributor
_,I,N,t	Interrupt Error	Error in firmware program flow.	Contact distributor
b,A,t,t,E,r,r	Battery Error	Battery has become depleted	Reconnect external power and press Backup Enable button.
b,A,t,t,,,L,O	Battery Low	Backup Battery < 8.6V during self test.	You may continue to use the Stimulator. The internal battery will charge during use.
E,b,a,t,E,r,r	Emerg. Batt Error	Emergency Battery self test failed.	Contact the Distributor, or your biomedical engineering department to replace battery
t,E,S,t ,E,r,r	Test Error	Self Test failure of stimulus generating or safety circuits.	Contact distributor
r,A,t,E],E,r,r	Rate Error	High Stim Rate detected. Unit has detected apparently unintended two pulses less than 300 ms apart. This may be due to noise on the Stimulator output (e.g. RF ablation voltage) or the communication cable.	Disconnect Stimulator from the patient. Check that communication cable between PC and Stimulus Generator Unit is secure and remove any interference from the Stimulator outputs. Reset Stimulus Generator Unit by pressing 'Backup Enable'. If error persists contact distributor.
,d,c,,E,r,r	DC Error	DC Output detected. This may be due to output channel failure or noise on Stimulator output (e.g. RF	Disconnect Stimulator from the patient. Remove any interference from the Stimulator outputs. Reset

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Error Message	Error Name	Explanation	Suggested action
		ablation voltage). This may cause unwanted arrhythmias.	Stimulus Generator Unit by pressing 'Backup Enable'. If error persists contact distributor.
_,t,o,L],E,r,r	Tolerance Error	Pulse Tolerance Error. More that 200 pulses were out of the +/- 25% tolerance limit.	Remove any interference from the Stimulator outputs. Reset Stimulus Generator Unit by pressing 'Backup Enable'. If error persists contact distributor.
N,o,P,C,E,r,r	No PC Error	No communication received from PC for a while. Due to failure of PC or disconnection of the communication cable.	Check that communication cable between PC and Stimulus Generator Unit is secure. Restart both the Stimulus Generator Unit and the PC by switching them off and on.
r,E,r,r ,E,r,r	Receive Error	Serial RS232 data link receive errors	Noise on the data link between Stimulus Generator Unit and the PC. Check the cable.

Table 9 Tabulated Error messages

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14 TROUBLESHOOTING

Micropace Stimulator software does not start on turning on the computer.

(i) If computer does not respond to the keyboard, check all cable connections and then restart the computer. If the computer still does not respond then the computer may need repair.

Pacing is not capturing and no stimulus artifact is seen.

- (i) If Atrium or Ventricle LEDs <u>are</u> flashing on the Stimulus Generator Unit on the appropriate channel:
 - ☐ If the Check Lead LED is flashing, then the Stimulator is most probably working correctly and there is a break somewhere in the catheter or wiring or, possibly but unlikely, pacing wire is not in contact with myocardium.
- (ii) If Atrium or Ventricle LEDs are not flashing on the appropriate channels:
 - If the Mains Power LED is not green, but is yellow, the Stimulus Generator Unit is switched OFF - switch it on at the rear panel. If the LED is not lit at all there is a problem with the power supply/mains power connection - check this and restore power.
 - Check the connection between the Computer and Stimulus Generator Unit.
 - Finally, change the Stimulus Generator Unit Mode to BACKUP MANUAL PACE mode by pressing the BACKUP ENABLE button. Press PACE ON/OFF once. If the Stimulus Generator Unit paces both channels and Atrium and Ventricle light, then there is a problem in the Computer or the communications link. Contact your Distributor for further help.

Patient is not capturing but a stimulus artifact is visible.

- (i) Consider current may be inadequate, try increasing current output.
 - □ If the Check Lead LED is flashing, then the pacing wire is not in contact or is touching infracted myocardium and needs repositioning or may have high impedance due to a broken conductor.

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15 MAINTENANCE

Basic maintenance requirements for safe continued operation of the system are listed here. Refer to the Technical Description for additional recommended preventative maintenance checks.

15.1 Batteries

Internal rechargeable batteries are replaceable only by service technician; refer to Label on underside of Stimulus Generator Unit, MP3008 for replacement schedule.

15.2 Maintenance and Calibration

- (i) Suggested weekly preventative servicing:
 - ☐ Inspect, clean and check the keyboard for correct operation.
 - □ Inspect all cables for damage such as crushing from trolley wheels.
- (ii) Perform annual preventative servicing described in Technical Description.

15.3 Cleaning Instructions

- (i) The Stimulator is not protected against ingress of liquids and the Operator should protect it from contamination, particularly by blood on the keyboard and spillage of fluids such as beverages.
- (ii) All Stimulator system components may be externally cleaned using a cloth dampened with standard hospital equipment cleaning agents such as 10% ammonia or 10% bleach, isopropyl alcohol, Cidex, or mild soap. Do not spray or pour agents onto the equipment and do not use acetone solvents.
- (iii) Cover Touch Screen with sterile plastic bag if it is to be part of a sterile field to prevent ingress of liquids or body fluids. To clean the touch screen, use window or glass cleaner.

15.4 Serviceable Life and Disposal

- (i) The Stimulator system has an expected supported life span of 7 years.
- (ii) Upon decommissioning, dispose of lead acid battery in MP3008 in an approved disposal or recycling facility. Further information available at www.micropace.com.au.
- (iii) EU-wide legislation as implemented in each Member State requires the waste electrical and electronic products carrying the mark (right) must be disposed of separately from normal household waste. This includes monitors, and electrical accessories, such as signal cables or power cords. When you need to dispose of you Micropace Stimulator, please contact the Distributor or Micropace directly.



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