USER INSTRUCTION MANUAL

& TECHNICAL DESCRIPTION

Micropace Cardiac Stimulators

EPS320B/BT

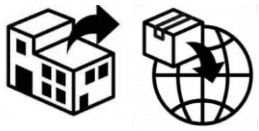
StimCor™

StimLab™

CE 2797

UKCA 0086

ENGLISH



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CH REP

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. MP3395
Global Version English 2.9, Date: 29/05/2025
Valid for:
Stimulator Software version 4.0+
SGU Firmware versions 4.76
https://micropaceep.com/customer-support/downloads/

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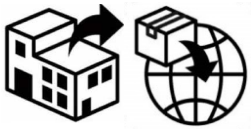

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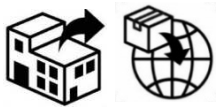

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Glossary and Terms

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, S3…S7.
GUI	Graphical User Interface

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

A reference package, comprising of a manual and a leaflet, is provided with the Cardiac Stimulator; a service manual is available on request. Included in the package are:

- User Instruction Manual / Technical Description (this document)
- Accessories Unit Contents and Instructions for Use Leaflet

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.

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

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 0.1mA to 25mA, duration of 0.5ms to 10ms and with a maximum voltage of ± 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

Higher series resistance reduces maximal attainable pulse current amplitude; lower shunt resistance reduces delivered current in all ranges; reduced frequency bandwidth may alter efficacy of stimulation at any current level and higher RF energy exposure may activate over voltage safety elements, reducing RF energy delivery and overheating within the stimulator system's Stimulus Connection Box.

Subject to these requirements, the Micropace Stimulator is intended for use with the following equipment; the user should contact Micropace Pty Ltd for compatibility information prior to use of other equipment:

Diagnostic pacing electrode catheters

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

Ablation electrode catheters

- The EPS320 Cardiac Stimulator is tested for use with a number of legally marketed RF ablation catheters. Contact Micropace Pty Ltd for further information (Refer also to "Warnings and Precautions" section below).

EP Recording equipment

- Computerized EP Recording systems manufactured by Bard Electrophysiology (LabSystem™ Duo™ and LS Pro™) and GE/Prucka (CardioLab 4000, 7000) have been tested for use with the EPS320 Stimulator.

RF Ablation Equipment

- RF ablation equipment manufactured by EPT (EPT1000XP) and Medtronic (Atakar RF Generator) have been tested for use with the EPS320 Stimulator.

1.3 Important Patient Safety Warnings

Throughout this document, a **Warning** is intended to indicate a potential hazard or unsafe practice which, if not avoided, could result in death or serious personal injury, while a **Caution** conveys a potential hazard or unsafe practice which, if not avoided, could result in minor personal injury or product/property damage.

1.3.1 General Warning

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

- Cardiac Diagnostic Stimulators are used in medical procedures, during which intentional or unintentional life-threatening cardiac arrhythmias are likely to occur. 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 and the operation of this Stimulator, in an appropriate hospital facility.
- The supervising physician must verify all Stimulator settings immediately prior to commencement of pacing, with particular attention to any adaptively calculated S1 pacing

interval settings, and in the case of StimLab™, in case settings were altered using the alternate controller.

Warning: Installation and use only by qualified personnel.

- In order to prevent electrocution hazards or impaired performance of the Stimulator from incorrect installation, 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. The Stimulator system is a diagnostic tool for provocative electrophysiological testing of the human heart. The Stimulator system is not intended, designed or fit for the purpose of life support. Two levels of backup pacing for bradycardia are provided in case of failure of normal functioning of the Stimulator and are for use in non-life-threatening bradycardia; in case of life-threatening bradycardia, pacing with a temporary external pacemaker must be established immediately.
- A backup temporary external pacemaker must be immediately available for use in case of the occurrence of a life-threatening bradycardia. It should preferably be connected directly to an intracardiac electrical catheter located in a ventricle, bypassing any switching apparatus in case of failure or inappropriate settings of such switching apparatus.

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.
- For StimLab™ and StimCor™, in order to comply with IEC60601-1 and avoid possibility of patient / operator shock from accidental connection of Stimulator computer parts directly to mains power, ensure that Isolation Transformer has Mains Cord Retaining Bracket MP3181 installed.
- For StimLab™, in order to avoid electrocution hazards or loss of normal device function, ensure that the StimLab™ Bedside Remote Controller Station touch screen has its DC Power Plug Cover securely attached by screws, preventing accidental disconnection of its DC power plug and preventing insertion of a mains lead plug; this part must only use low voltage DC power input and must never be connected to mains power.
- Provided above isolated mains supply warnings are complied with, the complete StimLab™, StimCor™ or EPS320 system may be located within the patient environment.

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

- To avoid electrocution hazards, the Stimulator system may be connected to parts specified by Micropace as compatible or to other equipment provided the other equipment is also isolated from the mains. It must comply with electrical safety requirements of IEC60601-1 standard or equivalent, is legally marketed in the country and is CE marked for installations in the EU countries.
- Do not connect equipment other than that specified by Micropace to the multiple socket outlets on the Micropace supplied Isolation Transformer.
- If this Stimulator System is modified, reconfigured or has other equipment connected to it or to its isolation transformer, the hospital or the Responsible Organisation must perform appropriate inspection and testing, including to EN60601-1.

- 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. If unexpected results are observed or the SM-Box FAULT indicator lights, do not use the SM-Box; if urgent pacing is required, use the Emergency Bypass output socket and pace Ch2 (Ventric), or use Emergency Pacing on the Stimulator.

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).

- Use only supplied Stimulus Connection Box (MP3014) or optional Stimulus Multiplexer Box (MP3086) components to connect Stimulator's stimulus output to patient circuits. These components contain RF suppression filters to prevent large RF energies from RF Ablation equipment not equipped with RF filters from reaching the Stimulator output circuits. Use of other, including custom made connectors may bypass RF filtering and potentially lead to repeated alarms and shutdowns of the Stimulator and possible induction of unintended life-threatening arrhythmias during delivery of RF ablation energy.
- 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 the Stimulator away from dust, excessive heat or humidity, direct sunlight and splashing liquids and in a well-ventilated place.
- To ensure that operator may see important error messages displayed during operation, install with the front panel of the Stimulus Generator Unit visible to the Operator, as important error messages may be displayed during operation.
- 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 14,000 ft 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 (green MAINS POWER LED should blink) and in Standby Mode to ensure that backup battery remains fully charged. The computer should be switched off.
- Assembly and modifications of this Medical System during the actual service life require evaluation to the requirements of EN60601-1.

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 and check that Emergency Fixed Rate Pacing and the Stimulator generally functions correctly.
- 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.

- 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.
- To ensure reliable stimulus capture, set stimulation current according to capture threshold whenever changing stimulation site or catheter. Two times threshold is usually used.
- Use of excessive stimulation currents may induce fibrillation and produce misleading results in ventricular stimulation studies.
- To reduce chance of accidentally inducing ventricular fibrillation, ensure reliable ECG sensing from correct source and use SYNC_TO function to avoid stimulating in the vulnerable diastolic period where appropriate.
- When using ECG-synchronous stimulation, to improve efficacy and prevent unwanted induction of arrhythmias, ensure that the ECG signal and detection of PQRS are satisfactory before and during pacing.

Caution: The Stimulus Generator Unit should be charging its backup battery while not in use.

- The Micropace stimulator should be connected to external power; its Power switched on at the rear panel switch and in the Standby Mode while not in use to ensure that backup battery remains fully charged.
- The Stimulator should be maintained according to “Maintenance” section of this manual.

1.5 Adverse Events[1]

The StimLab™ / ESP320 produce standard cardiac stimulation outputs similar to other existing programmable cardiac stimulators in use for the past 30 years; there are no known adverse effects from short term diagnostic use of such stimulation when applied correctly. Following is a list of potential adverse events from Stimulator device malfunction or human error (in alphabetical order):

- Arrhythmia
- Death
- Explosion or fire
- Myocardial injury
- Operator electrocution

Refer to above Warnings and Precautions.

1.5.1 Observed Adverse Events

Micropace stimulators produce standard cardiac stimulation outputs similar to other existing programmable cardiac stimulators in use for the past 30 years. The standard pulse output characteristics are well defined in standard Electrophysiology texts and the application, safety and clinical efficacy of this group of devices is well established in the medical field and in one recent review by McLaughlin et al ["Review of seven cardiac electrophysiology stimulators", by N.B.McLaughlin, C.J.Griffiths, R.W.F.Cambell et al in Physiol.Meas.,14 (1993) 57-69].

Report of adverse events related to EPS320 Micropace Stimulator arises from the following clinical experience with the product subject to product vigilance (device exposure estimated by adopting an estimate of 14 patients per stimulator per month of use, each patient exposed for an estimated mean time of 2.5 hours)

- Clinical use of the device in its evolving form since January 1998, evaluated in October 1999 by a survey of 6 clinicians using 6 Stimulators with an accrued clinical experience with the product on more than 1600 patients
- A prospective field trial of safety and efficacy of the EPS320 performed in May to July 1999 concurrently at 4 hospitals in Sydney, involving 6 Stimulators / cardiologist users and a total of 23 patients.
- Clinical use of the EPS320 in Australia and Southeast Asia from July 1999 to October 2001, involving 22 Stimulators and an estimated 7400 patients.
- Clinical use of the EPS320 in EC countries from January 2001 to October 2001, consisting of 17 Stimulators accumulating clinical exposure to an estimated 2400 patients.

The EPS320 Stimulator has thus been used on an estimated total of 10,000 patients, approximately half using the current firmware version, leading to an estimated device exposure of 25,000 hours.

No deaths or injuries related to the use of the EPS320 Stimulator have been reported during the device exposure.

Two adverse events were reported, both due to device interaction with an RF Ablation Generator. They were non-sustained Ventricular arrhythmias arising when operators simultaneously paced and delivered RF ablation energy through the same ablation electrode; the EPS320 Stimulator detected the interaction and shut down in both cases. Device interaction has been eliminated in the field by the issue of a Safety Alert warning against this application and the addition of RF filters to Stimulator's Stimulus Connection Box to isolate Stimulator from RF signals.

1.5.2 Potential Adverse Events

Following is a list of potential adverse events which could be directly associated with diagnostic cardiac stimulation using the stimulator during electrophysiological studies (in alphabetical order):

[1] Sections 1.5 – 1.8 for US Market only

Bradycardia or asystole

- Should a patient develop bradycardia or asystole during the use of the Stimulator, failure to promptly backup pace the patient may lead to hypotensive injury within seconds to minutes. Such arrhythmia may typically occur (i) in patients with atrio-ventricular conduction defects, (ii) during placement of intra-cardiac electrode catheters, (iii) after cardioversion/defibrillation or (iv) during RF ablation.
- The Stimulator may fail to normally deliver stimuli due to (i) power failure or power interruption, (ii) failure of PC, (iii) loss of communication between PC and Stimulus Generator Unit (SGU), e.g. due to lead disconnection or (iv) failure of SGU itself due to spontaneous fault or damage from external events such as defibrillation of RF ablation energies.
- To avoid patient injury, the user may use the battery powered Backup Manual Pace mode in case of power failure, failure of PC or the communication link, and the Emergency Fixed Pacing mode in case of failure of normal operation of the SGU. The Micropace Stimulator is not a life-support device; these functions are for use in non-life-threatening bradycardia or until external temporary pacing is established in case of asystole. Refer to “The EPS320 Stimulus Generator Unit” section below for instructions on the use of these features.
- DC voltages greater than 5000V or RF voltages greater than 350V pp applied to Stimulator outputs may cause circuit failure; the Stimulator issues a range of alarms in case of failure of output circuits – see Section “Hardware Error Messages on the Stimulus Generator Unit.”

Explosion or fire

- Explosion could arise from accumulation and ignition of explosive gasses vented from charging of the backup battery within the Stimulator. Use Stimulator only in well-ventilated areas.
- Explosion could also arise from electrical sparks within the Stimulator igniting explosive anesthetic gasses in the operating room. Do not use Stimulator in the presence of volatile anesthetic gasses.
- Continuous RF voltages greater than 350V pp applied to Stimulator outputs in contravention of labeling may cause overheating of the Stimulus Connection Box and possibly cause a fire hazard. Similar hazards would probably be present in other equipment with over voltage protection. Special care will be required should RF generators capable of delivering such voltages (corresponding to in excess of 150W into 300 Ohm load) become available.

Myocardial injury

- Excessive current flows through intra-cardiac electrodes, such as due to failure of Stimulator output circuit causing excessive stimulation currents and inadvertent shunting of defibrillation or RF ablation energies through a malfunctioning Stimulator or equipment attached to its outputs could theoretically cause localized myocardial damage at the pacing electrode.
- In order to minimize risk of myocardial injury, connect EPS320 Stimulator stimulation outputs only to legally marketed medical equipment compliant with IEC60601-1 and if error messages appear on the SGU, consult the section “Hardware Error Messages on the Stimulus Generator Unit.” prior to using the Stimulator again.

Operator electrocution

- The EPS320 Stimulator auxiliary signal input/output ports and RS232 communications port are optically isolated from patient circuits, but connect directly to Stimulator signal ground plane, in accordance with IEC 601-1. Connection of these ports to equipment without appropriate mains isolation or protective grounding may cause electrocution of the operator by mains-derived AC current in case of malfunction in the connected equipment.
- In order to minimize risk of electrocution to the operator, connect EPS320 Stimulator input/output ports only to legally marketed medical equipment, isolated from mains power and compliant with IEC60601-1.

Ventricular tachycardia or fibrillation

- The EPS320 Stimulator may be used to intentionally induce ventricular or atrial arrhythmias including ventricular tachycardia and fibrillation. Causes of inadvertent induction of such arrhythmias includes operator error, Stimulator malfunction and device interactions:

  (i) Myocardial stimulation with DC current.
  Stimulation of myocardium with DC current is likely to cause arrhythmias, including intractable ventricular fibrillation (if operator is unaware of the fault and does not remove the source from the patient, ventricular fibrillation may repeatedly recur after defibrillation, possibly leading to patient death). DC current flow in the stimulation circuit loop may potentially be caused by Stimulator output circuit failure, failure in other third party equipment inserted in the stimulation circuit loop or device interaction between interconnected equipment. Should the EPS320 Stimulator detect such a condition a DC-ERROR alarm is issued, (_,d,c,_,E,r,r displayed on SGU front panel and DC-ERROR alarm message on the computer), followed by a safe state shut down of the Stimulator. Refer to section “Hardware Error Messages on the Stimulus Generator Unit” below for instructions in this case. Regardless of Stimulator alarm state, recurrent unexplained ventricular fibrillation should prompt user to immediately disconnect the patient from the stimulation circuit, preferably at the intracardiac electrode catheter connectors.

  (ii) Intended cardiac stimulation in the vulnerable diastolic cardiac period.
  User should ensure that ECG sensing by the Stimulator is reliable and always use the SYNC-TO function set to PQRS to avoid stimulating in the vulnerable diastolic period, where appropriate. External amplified ECG signal is the recommended source of ECG, however, where external ECG source is not available or unreliable, the EPS320 Stimulator may be configured to sense intra-cardiac ECG from either of the stimulation output channels.

  (iii) Inappropriately rapid cardiac stimulation.
  Cardiac stimulation at rapid intervals, typically less than 300 ms, may cause undesirable arrhythmias including ventricular fibrillation. Inadvertent rapid stimulation may occur either through user error, inappropriate Stimulator software safety parameter configuration or Stimulator hardware or software malfunction. The Stimulator’s SGU monitors for un-programmed rapid stimulation and if detected, issues a Rate Error alarm, followed by a shut down safety state. Monitor the Stimulator function, patient’s ECG and observe the patient continuously for unexpected behavior whenever patient is connected to the Stimulator; disconnect the patient from the Stimulator and do not use if abnormal stimulation is observed.

  (iv) Un-programmed isolated stimulation pulses.
  Unintended cardiac stimulation with isolated stimulation pulses may cause undesirable arrhythmias including ventricular fibrillation. Isolated stimulation pulses may potentially occur due to Stimulator hardware or software malfunction. The Stimulator’s SGU monitor detects un-programmed stimulus pulses occurring within 300 ms of another stimulus pulse and issues a Rate Error alarm, followed by a shut down safety state. Monitor the Stimulator function, patient’s ECG and observe the patient continuously for unexpected behavior whenever patient is connected to the Stimulator; disconnect the patient from the Stimulator and do not use if abnormal stimulation is observed.

  (v) Mains derived AC current microshock.
  Mains derived AC leakage currents to ground may cause patient microshock leading to arrhythmias, including intractable ventricular fibrillation. AC leakage currents may potentially arise from a malfunction in the EPS320 Stimulator or connected third party equipment if the mains power supply is not isolated in all interconnected equipment. Ensure that the Stimulator, including the PC and all connected third party equipment is connected only to isolated mains power supply.

1.6 Summary of EPS320 Stimulator field trial

Introduction:

The core of the Micropace cardiac stimulator systems, the EPS320 Cardiac Stimulator, were validated earlier in the clinical setting in conjunction with other equipment while operated by a sample of end users and subjected to typical sources of potential interference, such as Radio Frequency (RF) ablation energies and DC cardioversion. Validation end points were the absence of adverse events during the procedure, demonstration of adequate pacing in all protocols for the duration of typical Electrophysiological (EP) study and RF ablation procedure without interruption, adequate sensing of QRS, subjective scoring of fitness for purpose by user and freedom from error states.

Patients studied:

23 clinically indicated EP studies with or without RF ablations in 23 patients in routine clinical settings. A total of 6 operators used the EPS320 Cardiac Stimulator in 4 different hospitals.

Methods:

The protocol consisted of the collection of data on Stimulator clinical performance by a trained observer during routine clinically indicated EP studies by cardiologists. Sequential patients were chosen and no change to the routine clinical management of patients was made.

Device performance was assessed qualitatively with defined pass criteria for each case study and defined criteria for overall device pass or fail for each application.

Results:

Data was collected from 23 EP studies, consisting of 10 cases of RF ablation of supraventricular tachycardia(SVT), 4 studies of ventricular tachycardia (VT) , 3 syncope studies and 6 other study types. The Stimulator was used during delivery of RF ablation energies in 14 of the cases and during DC cardioversion of patient on 6 occasions in 4 patients. Results are shown in Table US-1 below. No hazardous events or stimulator failures were observed; Stimulator functioned as per specification at all times in all cases.

Conclusions:

The EPS320 Cardiac Stimulator:

- Performs within acceptable safety parameters at all times.
- Performs substantially to the system requirements set out for the device and appears to satisfy Electrophysiologist's clinical requirements.

PARAMETER	TOTAL/ MAX	PASS
Nominal Protocol Stimulator performance (all must pass)		**23/23**
All programmed pacing stimuli are delivered (all = pass)	-	23/23
Adequate capture achieved (all expected = pass)	-	23/23
Adequate sensing: 4:>90%, 3:70-90%, 2:50–70%, 1: <50% (>70%=Pass)	74/105	22/22
Upper and lower limits of variables satisfactory for clinical purpose? (Ask clinician)	-	23/23
Did Sync-to-QRS function correctly- pacing started on all first (detected) QRS?	-	8/8
Performance during tachycardia (all must pass)		
Adequate sensing4:>90%, 3:70-90%, 2:50–70%, 1:<50% (>70%=Pass)	53/85	18/18
Performance during RF ablation (all must pass)		
No Stimulator Error during ablation	14/14[1]	14/14
Operator able to recover Stimulator from error	-	-
Performance during defibrillation (all must pass)		
Number of defibrillations during study;	6	-
Record of any malfunction (no., none = pass)	0	6/6
Failure modes(all must pass)		
Did error codes appear on Stimulator Unit? (No=Pass)	0	23/23
Loss of communication between PC and Unit occurred? (No=Pass).	0	23/23
If communication lost, was it re-established easily? (Yes=Pass)	0	23/23
Record of any computer freeze or unexpected behavior as well as any display anomalies, (None = pass).	0	23/23

PARAMETER	TOTAL/ MAX	PASS
Test of Backup Manual stimulation(all must pass)		
Did Interval and Current adjustments work and pacing stimuli work? (Yes= pass)	6	6/6
Did all stimuli capture patient; (all = pass)	6	6/6
Emergency fixed pace operation worked (all stimuli issued)	6	6/6
User performance Score (5=very good, 4=good, 3=adequate, 2=poor, 1-unsatisfactory)		
User-friendliness of computer user interface (self-evident menus/operation)	71/80	16/16
Ergonomic (speed, ease, minimum number of steps) of operation.	70/80	16/16
Overall Safety of operation.	72/80	16/16
Reliability of operation, lack of breakdowns, delays.	75/80	16/16
Fit for purpose of EPS Stimulation (essential features)	75/80	16/16
Comprehensiveness of features within system (all desired features)	73/80	16/16
Flexibility of use (adaptability to non-standard/new uses)	60/70	13/13

Table US-1 Results for individual measured parameters

Notes for Table US-1 above

[1] During one study, the Stimulator entered Fail Safe operation mode due to a false alarm without causing hazard to the patient after the pacing electrode inadvertently directly contacted the RF Ablation electrode during application of RF energy (the Stimulator alarm was subsequently modified, validated and appropriately labelled as per current labelling).

1.7 Individualization of treatment & Patient Counseling Information

- Pacing threshold in each chamber studied should be established prior to the EP study and stimulation current should be set at twice the pacing threshold or 1mA, whichever is greater. Pacing thresholds may differ with different catheter positions and presence of myocardial scarring.
- Adequate ECG / IECG signal should be derived from the patient to enable stimulation triggering. External amplified IECG signals should be the first choice but catheter-tip IECG may be used otherwise. Output level of the IECG source or Micropace Stimulator input gain should be adjusted to obtain optimal IECG / ECG.
- To our knowledge, the StimLab™ requires no specific counseling in addition to standard patient consent by the clinician for the overall EP Study or RF Ablation procedure during which it is to be used.

1.8 References

(1) AHA Medical/Scientific Statement: ACC/AHA Guidelines for Clinical Intracardiac Electrophysiological and Catheter Ablation Procedures. *Circulation*. 1995;92:673-691

(2) Adams, D.E: Setting Up the Laboratory for Ablation. Catheter Ablation of Arrhythmias. D. Zipes ed. Futura Publishing Company, Inc., Armonk, New York. 1994: 89-90.

(3) Josephson, ME: Clinical Cardiac Electrophysiology: Techniques and interpretations. 2nd Edition. Lee & Febiger, Pennsylvania, 1993:pp10,67.

(4) McLaughlin, NB Griffiths CJ, Campbell RWF and Murray A. Review of Seven cardiac Electrophysiology stimulators. Physiol.Meas. 14 (1993) 57-69.

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 and 2007/47/EEC (Medical Device Directive)
- 93/68/EEC (CE Marking Directive)

CE 2797

Issuing Notified Body: BSI group.

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

- EN/ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes
- IEC 60601-1:2005/A2:2020 Medical electrical equipment — Part 1: General requirements for basic safety and essential performance
- EN/IEC 60601-1-2:2014, FCC Part 15 Subpart B and Canada ICES-003 Issue 7 (EMC)
- EN/IEC 60601-1-6:2010 (Usability)
- EN/ISO 14971:2019 Medical devices — Application of risk management to medical devices

3 COPYRIGHT, WARRANTY AND DISCLAIMER NOTICE

Copyright Notice

Trademarks

The cardiac stimulator system is protected under applicable copyright laws. Purchase and use of this System is subject to the following agreements:

License Agreement

You may:

(i) use this program on only one computer at a time;

(ii) make a copy solely for the purpose of backup.

You may not:

(i) distribute copies of this program or documentation to others;

(ii) rent, lease or grant sublicenses to the program to others without prior consent from Micropace Pty Ltd.

Your license to use this program will terminate automatically if you fail to comply with the terms of this Agreement. A full copy of the license agreement can be found in the software.

Limited Warranty

Micropace warrants that, for a period of one year from the date of installation of the Product, the Custom Hardware will under usual use be free from defects in materials and workmanship.

The Software will, when properly used in accordance with this license, operate in accordance with its applicable specifications published by Micropace, be free of material defects and be fit for the purpose intended by Micropace.

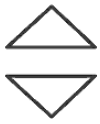
Micropace shall have no obligation to make repairs to, or replace, Products which are damaged by normal wear and tear, or which result from (i) catastrophe, fault or negligence of a person other than Micropace, (ii) improper or unauthorised repair, or (iii) causes external to the Products, including, but not limited to, power surges, extreme environmental conditions outside of specifications or mishandling, such as spillage of liquids within the Products. All claims for warranty services must be directed to your authorised Micropace distributor.

Except for the above express limited warranties, and subject to law, Micropace makes, and you receive, no warranties, express, implied, statutory, or in any communication with you; and Micropace specifically disclaims any other warranty including the implied warranty of merchantability or fitness for a particular purpose. Micropace does not warrant any of the third party hardware or that the operation of the product will be completely free from minor software or hardware inconsistencies.

The Stimulator must only be used by appropriately qualified and experienced personnel, in appropriate facilities and in conjunction with appropriate safety equipment as described in section “Important patient safety warnings” above. Micropace accepts no responsibility for any consequences arising out of the use of the Stimulator outside of these restrictions. The Operator should verify for him / herself that each function of the Stimulator performs to the Operator’s expectation prior to use of the Stimulator on patients.

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)
	Read Instruction for Use	Read Instruction for Use	On product label
	Contents	Contents	On shipping label.
	Component of	This is a component of a system.	On product label.
	Manufactured on	Manufactured on date: YYYY-MM.	On medical device product label.
	Manufacturer	Legal Manufacturer	As above in this manual. On product label.
	Country of manufactured	Country of manufactured which can be AU for Australia or US for USA	On package's shipping label
	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.

Symbol	Name	Meaning	Location
	Attention	Electrocution Hazard. In order to comply with IEC60601-1 and avoid possibility of patient / operator shock from accidental connection of Stimulator computer parts directly to mains power, ensure that Isolation Transformer has Mains Cord Retaining Bracket MP3181 installed at all times."	Isolation Transformer
	Attention	Connect only to Micropace supplied parts.	Next to AUXILIARY PORT on rear panel of SGU, MP3008.
	Warning	Not Suitable for direct connection to RF Ablation Power > 150W into 300 Ohms.	On MP3086.
CE 2797	CE Marking & Notified Body Identification	This item is in compliance with the requirements of the European Union Medical Device directives (MDD) and is labeled in accordance with the requirements of these directives.	1. Side of SGU, MP3008.
UK CA 0086	UK Marking & Notified Body Identification	This item is in compliance with the requirements of the UK Medical Device Regulation and is labeled in accordance with the requirements of the regulation.	IFU and Product/Shipping label of Universal and EU packages
CE	CE Marking	The commercially available Isolation transformer and Low voltage transformer supplied with each system fully comply with EMC and Safety Standards.	1 Isolation Transformer. 2 Low voltage Transformer.
UKRP	UK Marking	UK Responsible Person	IFU and shipping label of Universal and EU packages
0	Power OFF	Device is switched OFF; battery is NOT charging. Note that the MAINS light glows yellow to indicate that power is available to the device.	Next to **POWER** switch on rear panel of SGU, MP3008.
I	Power ON	Device is switched ON and battery is charging.	Next to **POWER** switch on rear panel of SGU, MP3008.
	Increase / Decrease	Increase / Decrease adjacent Interval or Current parameter.	On the front of SGU next to Interval Current displays, MP3008.
+	Positive Output	Positive stimulus output. Defibrillator CF Protected part.	Stimulus Connection Box, MP3014 or on Stimulus Multiplexer Box, MP3086.

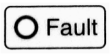
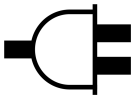
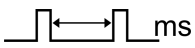
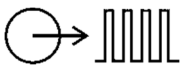
Symbol	Name	Meaning	Location
	Negative Output	Negative stimulus output, Defibrillator CF Protected part.	Stimulus Connection Box, MP3014 or on Stimulus Multiplexer Box.
	FAULT	Fault Detected in Stimulus Multiplexer Box – use Emergency Bypass.	On optional Stimulus Multiplexer Box, MP3086.
	Emergency Bypass	Emergency Bypass output socket - pace Ch2 (Ventric), or use Emergency Pacing on the Stimulator.	On Stimulus Multiplexer Box, MP3086.
	Backup Stimulator Here	Sign indicating location of Stimulator SGU MP3008 for backup pacing.	Next to where SGU MP3008 is installed.
	Distributor	Distribution medical device into the locale	On this manual
	Importer	Importation medical device into the locale	On this manual

Table 1 Explanation of symbols

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

Symbol	Name	Meaning	Location
	Mains Power	**No light:** No external power to SGU. **Orange Light:** Connected to Mains Power, but SGU switched off at Power Switch at rear. Battery is not charging. **Green Light**: Connected to Mains Power and SGU switched on – in Manual Backup or PC Pace Control modes. Battery is charging. **Green Light Flashing:** Connected to Mains Power and SGU in Standby state. Battery is charging.	Left Front Panel of Stimulus Generator Unit.
	Battery Power	SGU is powered by Battery.	
	Battery Low	Battery is nearly discharged. Connect to mains power to continue use of SGU.	
	PC Pace Control	SGU is under control of Computer. Use keyboard or touch screen, if fitted, to control pacing.	
	Backup Pace	Backup / Manual pacing controls are located here. This can be used to pace when not under control of the computer.	Left centre Front Panel of Stimulus Generator Unit.
	Pace On/Off	Press to toggle start / stop pacing.	
	Backup / Standby	Press to toggle between Backup Manual Pace Control and Standby.	
	Pace Interval	Basic pacing interval in ms.	
	Current	Current amplitude of stimulus.	
	Pace Output	Stimulus output and indicator lights are here.	Right centre Front Panel of Stimulus Generator Unit.
	Ch1 (Atrium)	Green flash: Stimulus into Channel 1, usually located in Atrium.	

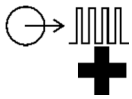
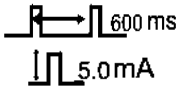
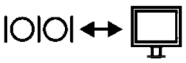
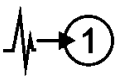
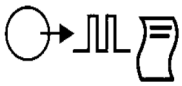
	Ch2 (Ventric)	Green flash: Stimulus into Channel 2, usually located in Ventricle.	
	Check Lead	Stimulus current not able to be delivered because of a break in the electrical lead / circuit.	
	Emergency Fixed Pace Output	Plug green patient connection cable into this socket to immediately pace Ventricle Ch2 at 100ppm @ 5mA. Note: Ch1 Atrium is not paced.	Right Front Panel of Stimulus Generator Unit.
	Pace V at 100ppm @ 5mA	As above.	
	Pace V Ch2	Green flash: Stimulus on Channel 2, usually located in Ventricle.	
	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.	Rear panel of Stimulus Generator Unit.
	Computer Link Port	Port for connection to controller computer; use Micropace cable only.	
	Auxiliary Port	Port for connection to Stimulus Multiplexer Box; use Micropace cables only.	
	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.	
	Replace	Replace battery on specified date with specified batteries.	Battery Replacement Label on SGU.
	Battery	Contains Batteries.	

Table 2 Explanation of symbols – specific to the SGU, MP3008.

5 EPS320 FAMILY OF CARDIAC STIMULATORS

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

5.1 Description of system

The EPS320 Cardiac Stimulator by Micropace Pty Ltd. is a diagnostic external programmable cardiac stimulator.

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

The Stimulus Generator Unit is mains-powered via a DC power supply and has an internal trickle-charged backup battery in case of power failure. Its outputs are defibrillator and RF energy protected and it features external ECG input ports as well as catheter-tip ECG sensing for triggering of pacing events and one trigger output channel for synchronization with other equipment. The system is powered from the mains via a medical grade isolation transformer.

The EPS320 software allows interactive programming of all aspects of the pacing stimulus: the current amplitude, pulse width, delivery to channel 1 or 2 or both, and all stimulus parameters including drive train number, timing and up to 6 extra-stimuli. The stimulator has an intuitive user interface, with all commonly used stimulus and pacing protocol parameters located on fixed menus on the one screen instantly adjustable via hotkeys including during actual pacing. All standard EP stimulation protocols are available pre-programmed but may be reconfigured and automated according to user requirements.

The EPS320 system may be enhanced with a number of optional kits, including:

(i) Stimulus Multiplexer Box (SM-Box) which converts the two stimulus output channels to four output channels by automatic reprogramming and switching of stimulus generator outputs,

(ii) Touch Screen Kit, which adds a touch screen interface to keyboard control of the stimulator, and

(iii) StimLink™ Kit, which offers integration with certain EP recording equipment.( )

6 EPS320B/BT CONFIGURATION

6.1 Description of system

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

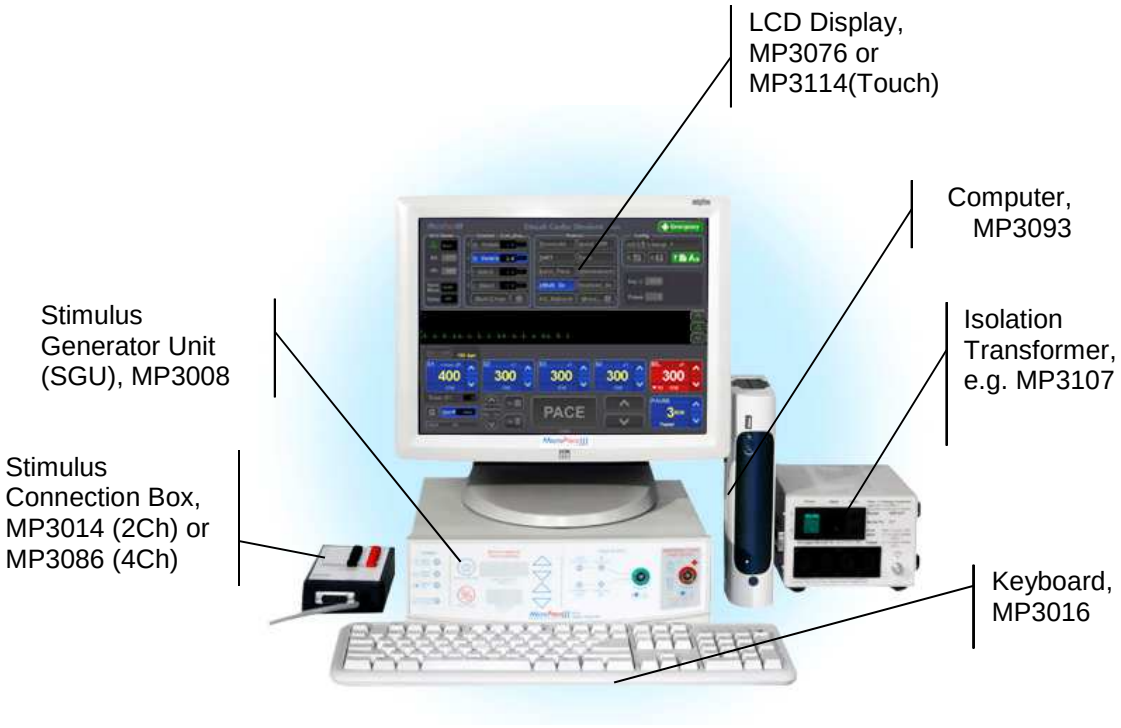


Figure 2 EPS320B/BT Configuration

6.2 Packing List

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 and connection diagram below. (For system with optional LCD Touch Screen Kit, MP3113, please refer to its instructions). Note that some distributors include some Stimulator Options as standard; refer to the packing list with the product.

EPS320B STIMULATOR & PC CARTON (MP3102)		
Item	Part No.	Qty
Isolation Transformer Box:		
Isolation Transformer, 110-240V 300VA	MP3107	1
Accessories Box:	MP3055	1
Power Supply for SGU only	MP3074	1
Stimulus Connection Box with RF Filter	MP3014	1
Isolation Transformer Power Lead, according to Country	MP3059EU/US[1]	1
Cable Serial Boost RS232	MP3033A	1
Isolated Mains Power Lead, IEC 3 to 2 Pin- EU or US Style	MP3066EU/US[1]	1
Cable Signal – 6mm Phono-plug terminated	MP3034	1
Signal Cable, BNC to Phone plug	MP3109	1
Isolated Mains Power Lead (IEC3 to 3 Pin)	MP3030	1

EPS320B STIMULATOR & PC CARTON (MP3102)		
Accessories Booklet	MP3064EU/US[1]	1
Installation Kit	MP3063	1
Keyboard with key labels	MP3016	1
Bona Light PC Computer	MP3093	1
Power Supply for Bona Light PC	MP3335	1
Stimulus Generator Unit (SGU)	MP3008	1
Documentation:	-	
User Instruction Manual	MP3395	1
Installation Procedure Booklet	MP3069	1
Manufacturer's Test Certificate	-	1
Summary of Hotkeys	-	1
Language Support Pack	MP3149[3]	1

R_Packing List-EPS320B-EU3.1.doc 2.8.10

NEC LCD Screen Carton 2		
Item	Part No.	Qty
LCD Display (Micropace Part No. MP3076)	LCD52V	1
Video Signal Cable (Part of Micropace No. MP3076)	-	1
NEC LCD Screen Instruction Manual	-	1
Isolated Mains Power Lead, (IEC 3 to 3 pin)	MP3030	1

PackingList-NECMonitor-MP3076- 2.5EU.doc-27.04.06

Note 1: Cable part numbers end in EU for 240V versions and US for 110V versions.

Note 2: May be replaced by optional Micropace Touch Screen Kit, MP3113.

Note 3: Only available with European system configuration.

6.3 EPS320B/BT Installation

Following is a summary of how to assemble the standard EPS320 Cardiac Stimulator. Installation of this Stimulator and any optional accessory kits is to be performed only by Micropace's or its Distributors' trained technical personnel, guided by special installation instructions contained in each product.

6.3.1 Unpack containers

Remove components from EPS320 Carton and LCD Display Carton and inspect for missing or damaged items. Verify the contents of the cartons against the enclosed packing lists. Most configurations contain the following items:

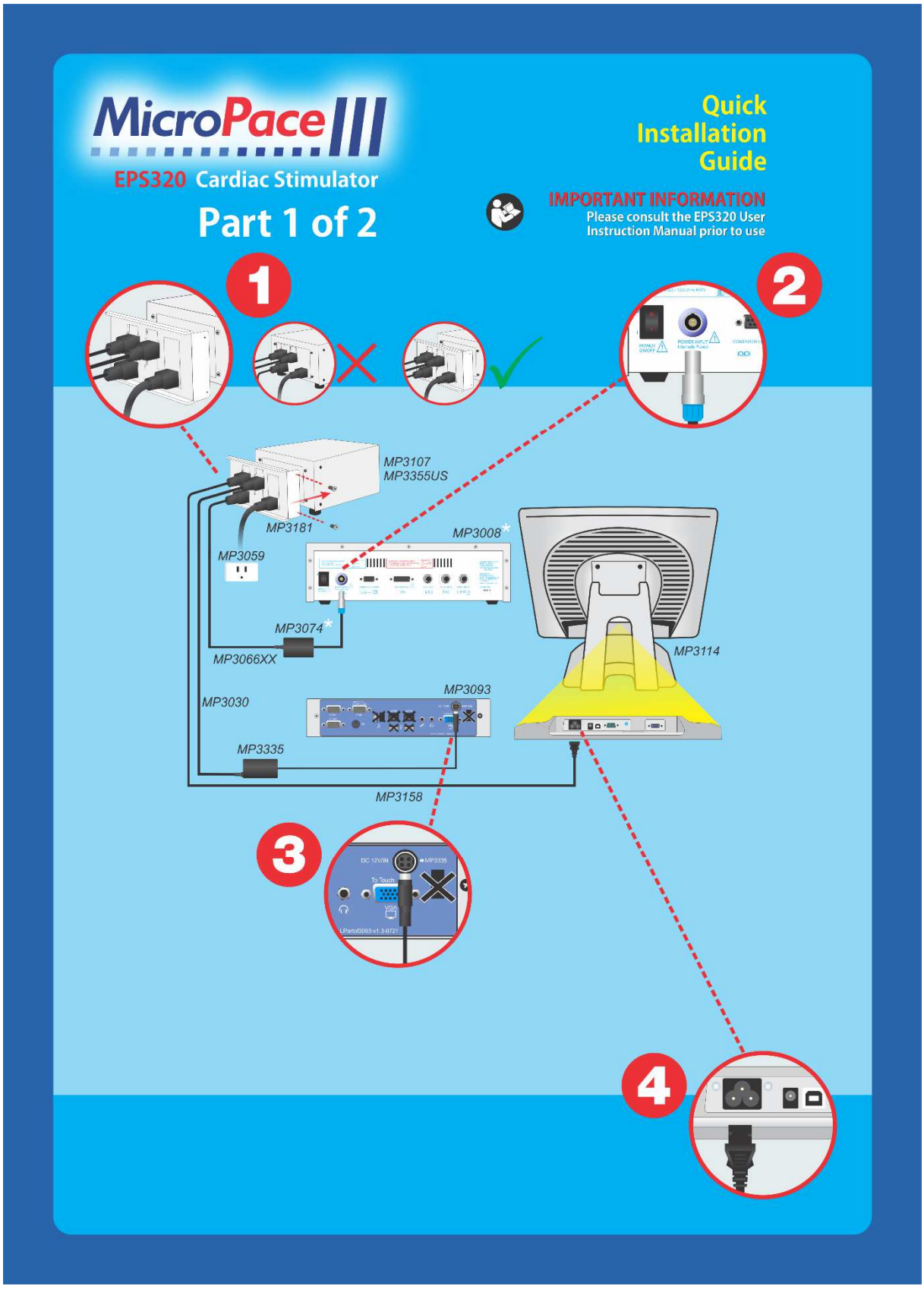
- Computer and LCD display and their accessories
- EPS320 Stimulus Generator Unit (SGU) and its power supply
- Mains Isolation Transformer (110-240VAC) and required mains cables
- Serial RS232 communication cable for connecting SGU to Computer
- Stimulus Connection Box for outputting the stimulus pulses
- ECG input signal cables for connection to your EP recording system.

6.3.2 Connect System Components

Read this manual completely before assembling the system, particularly Safety Warnings and Precautions above. Connect the system components as shown in Figure 3: EPS320 System connection diagram below.

Connect mains power to the PC and monitor via the Mains Isolation Transformer provided, part No. MP3107 (110-240VAC mains voltage). For patient safety, neither the computer nor the monitor must ever be connected directly to mains power supply. Other equipment not specified by Micropace shall not be connected to the Isolation transformer.

Connect the SGU Power supply, part No. MP3074 to the blue Power socket on the rear panel of the Stimulus Generator Unit and connect its mains lead to the isolation transformer MP3107 output. Connect the COMPUTER LINK PORT on the rear panel of the Stimulus Generator Unit to the serial COM1 port of the computer via cable MP3033A provided.


MicroPace III
EPS320 Cardiac Stimulator
Part 1 of 2
Quick Installation Guide
IMPORTANT INFORMATION
Please consult the EPS320 User Instruction Manual prior to use
1
2
3
4
MP3107
MP3355US
MP3181
MP3059
MP3008*
MP3074*
MP3066XX
MP3114
MP3030
MP3093
MP3335
MP3158

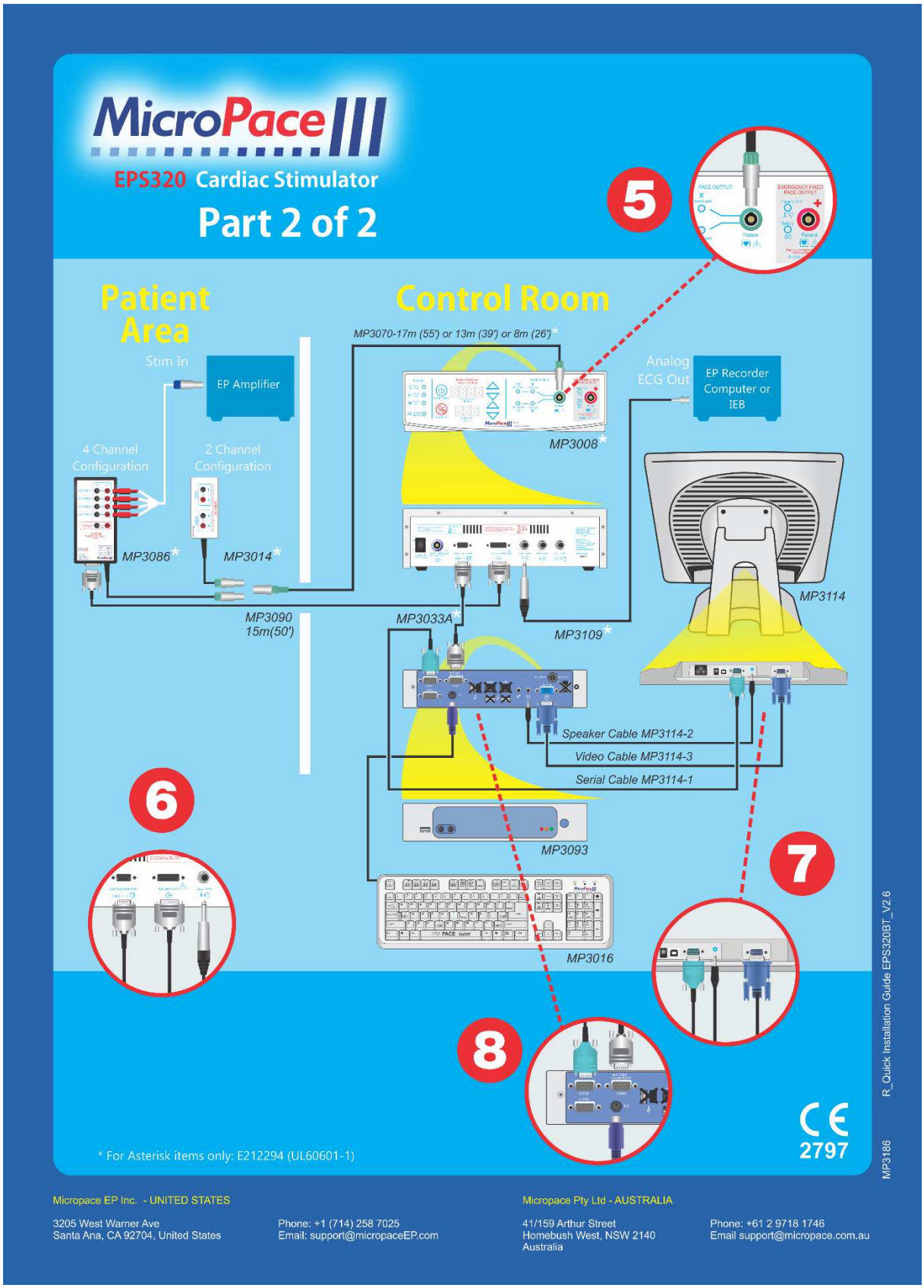


Figure 3: EPS320 System connection diagram

EPS320B/BT Optional Installation Accessories

The following optional installation accessories are available from Micropace. Note that some distributors include some Stimulator Options as standard; refer to the packing list with the product.

Part Number	Name	Description
MP3114 MP3113 (kit)	Touch Screen Kit	ELO Entuitive Touch LCD Screen for control of Stimulator by touch.
MP3086 MP3091 (kit)	Four Channel Multiplexer Kit	Alternative PC-controlled Stimulus Connection Box with four Stimulus Channel Outputs 1-4; EPS320 re-programs and switches the two physical Stimulus Generators between the four outputs to create a virtual Four-channel Cardiac Stimulator.
MP3096 (kit)	StimLinkTM Kit for communication with EP Recorder.	Opto-isolated outgoing RS232 communication channel for connection with EP Recorder with corresponding Software receiver. Broadcasts selected protocol, raw stimulus intervals and pacing channel for inclusion in Stim Logs. No patient or diagnostic data are broadcasted.
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 for use when EPS320 is located remotely to the patient, eg. in a control room of the EP Laboratory.
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 for use when EPS320 is located remotely to the patient, eg. in a control room of the EP Lab and customer wants to locate SGU near patient and PC/LCD Screen in a control room.

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

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.

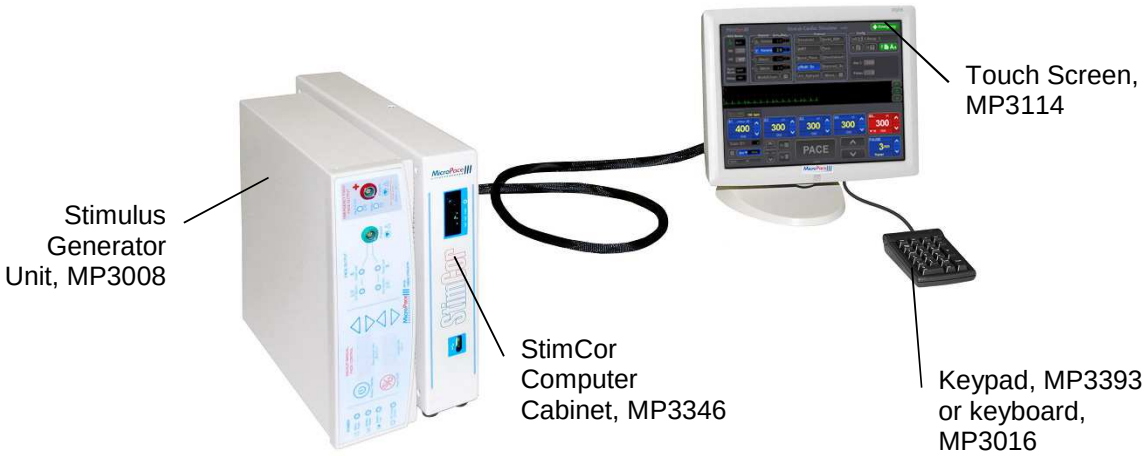


Figure 4 StimCor™ System Components

7.3 Packing List

STIMCOR™ SGU PACKAGE CARTON (MP3344)		
Item	**Part No.**	**Qty**
Isolation Transformer Box:		
Isolation Transformer, 110-240V 300VA	MP3107	1
Accessories Box:	MP3349	1
Cable Signal – 6mm Phone-plug terminated	MP3034	1
Signal Cable, BNC to Phone plug	MP3109	1
Isolation Transformer Power Lead, US configured	MP3059US	1
Isolation Transformer Power Lead, EU configured	MP3059EU	1
Stimulus Connection Box with RF Filter Serial No. [ ]	MP3014	1
Installation Kit:	MP3063	1
Isolation Transformer outlet retainer bracket	MP3181	1
Accessories Booklet	MP3182	1
Keyboard with key labels	MP3016	1
Stimulus Generator Unit (SGU)	MP3008	1
Documentation Satchel with User Instruction Manual	MP3347	1

R_PackingList MP3344-StimCorSGU Package_V1.5.doc

STIMCOR™ COMPUTER CABINET PACKAGE (MP3343)		
Item	**Part No.**	**Qty**
StimCor™ Computer Cabinet	MP3346	1
StimCor™ Computer Cabinet Instruction Leaflet	MP3378	1
Touch Screen AC Plug Cover	MC1019	1

R_PackingList MP3343-StimCorComputerCabinetPackage_V1.3.doc

Touch Screen (MP3113-B)		
Item	**Part No.**	**Qty**
ELO Touch Screen & accessories:	MP3114	1
Touch Video Cable, 2 m	Part of MP3114-3	1
Touch screen Serial Cable, 2 m	Part of MP3114-1	1
Speaker Cable, 2 m	Part of MP3114-2	1
Universal Cloverleaf IEC mains power connector lead IEC320 – C5 to C14	MP3158	1
Touch screen Stylus and holder	MP3133	1
Touch Screen Quick User Guide	MP3136	1

R_PackingList-MP3113-B-TouchScreen_V1.4.doc

7.4 StimCor™ Installation

7.4.1 Installation of cables

Install StimCor™ Computer Cabinet, EPS320 Stimulus Generator Unit (SGU) and Local Touch Screen in the control room. All cables are externalized from the Cabinet so you will not need to open the Cabinet during installation. The Cabinet has two cable bundles exiting it, (i) Local Touch Screen Cables and (ii) SGU Cables. refer to the steps below and diagram on the next page.

1. First connect the Local Touch Screen Cables - keyboard, local screen mains power, VGA cable and serial touch cable.
2. Next connect the SGU Cables – DC power cable and RS232 cable to the SGU.
3. Connect MP3059 mains cable to MP3107 Isolation Transformer and connect the transformer to mains.
4. At this point the Computer cabinet mains cable should be connected to the Isolation transformer. It is important that the mains lead is threaded through the Bracket MP3181 found in the Accessory box. The C14 connector should be inserted into one of the three available sockets on the Isolation transformer. Using a number 3 torx screwdriver secure bracket with the two torx screws, one on either side of the transformer.

Warning: In order to comply with IEC60601-1 and avoid possibility of patient / operator shock from accidental connection of Stimulator computer parts directly to mains power, ensure that Isolation Transformer has Mains Cord Retaining Bracket MP3181 installed at all times

5. Connect the rest of the Stimulator as per the StimCor™ Installation Quick Guide – Four Channel SM-Box MP3086 to MP3070 and MP3090 and Stimulus outputs on the MP3089 to EP Recorder Stimulator Inputs using shrouded 2mm plugs.

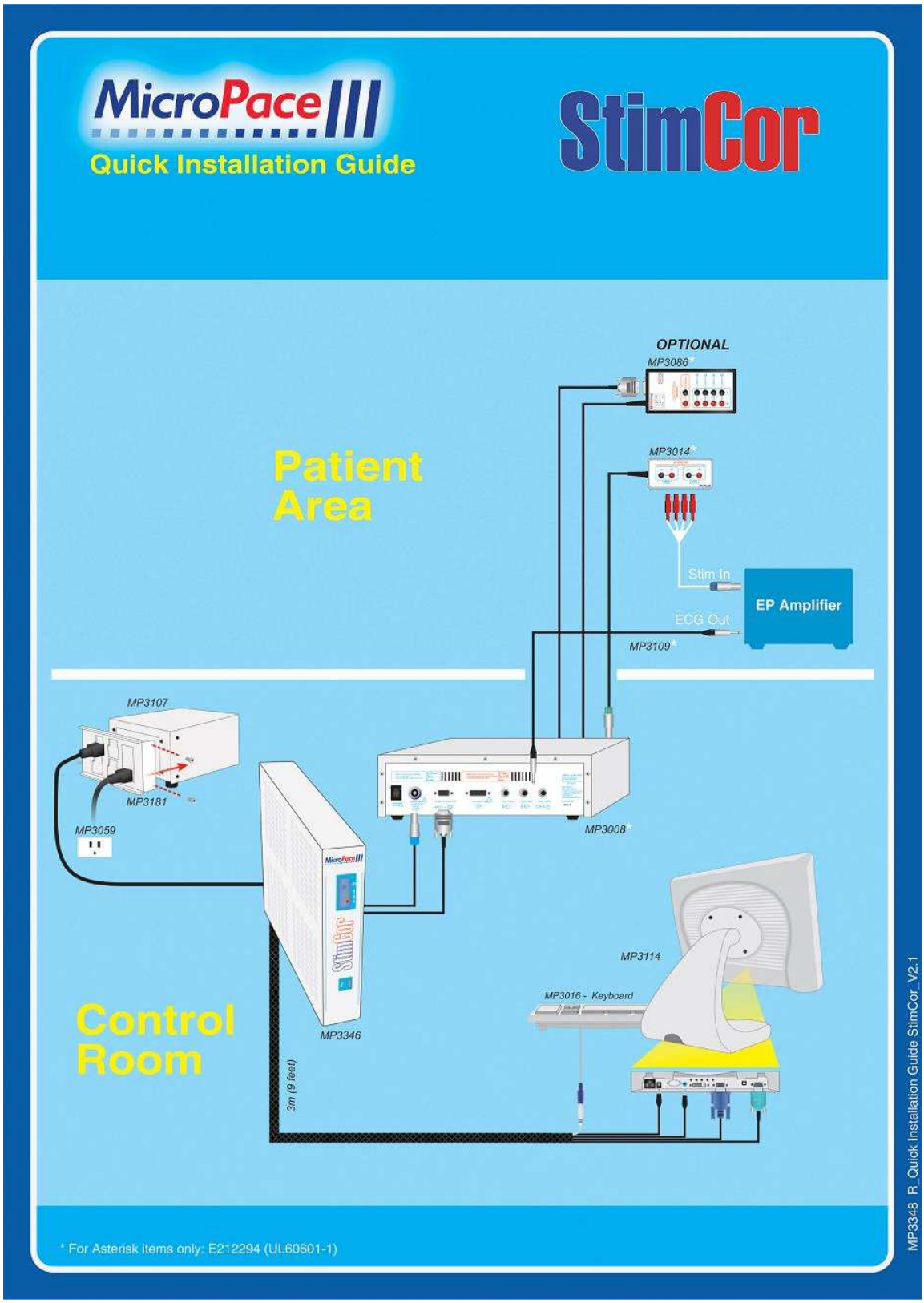


Figure 5 StimCor™ Installation Quick Guide

7.5 StimCor™ Optional Installation Accessories

Same as EPS320B/BT.

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.

Features:

- Uses the familiar EPS320 Stimulus Generator Unit and Graphic User Interface.
- Remote bedside touch screen with display of all settings and basic control of stimulation.
- Remote screen may be operated by a gloved hand through a sterile plastic cover.
- Remote screen mountable on a trolley, on optional roll stand or using its standard VESA on a monitor arm to suit lab.
- Single integrated 23-pin connector capable of instant hot-connection or disconnection to allow rapid stowage of remote controller when not needed.

The StimLab™ system has been designed to:

- Enhance Safety – Physician can see and verify Stimulator settings and operation at all times
- Assist with Staff training - Physician can demonstrate to and train Stimulator technicians from the bedside.
- Allow physician critical control – Physician can control or fine-tune stimulation himself in critical moments.
- Speed up communication – Technician and physician need not waste time communicating stim settings to each other, if the other person can now see them on their monitor.

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

8.3 Packing List

StimLab™ is shipped in four boxes, shown below:

StimLab™ & StimCor™ SGU Package (4 Channel) – MP3172		
Item	**Part No.**	**Qty**
Isolation Transformer Box:		
Isolation Transformer, 110-240V 300VA	MP3107	1
Accessories Box:	MP3179	1
Cable Signal – 6.5mm Phone-plug terminated	MP3034	1
Signal Cable, BNC to Phone plug	MP3109	1
Isolation Transformer Power Lead, according to Country	MP3059EU/US	1
Stimulus Multiplexer Box Serial No. [ ]	MP3086	1
Installation Kit	MP3063	1
Isolation Transformer outlet retainer bracket, for MP3107	MP3181	1
Accessories Booklet	MP3182	1
Keyboard with key labels	MP3016	1
Stimulus Generator Unit (SGU)	MP3008	1
Ultra Low Capacitance Stimulus Extension Cable Batch No. [ ]	MP3070-13	1
SM-Box Control Cable (15m) for MP3091–Batch No. [ ]	MP3090	1
Documentation Satchel with User Instruction Manual	MP3176	1

T_PackingList StimLab -MP3172-UniversalSGU Package_V1.5.doc

StimLab™ Computer Cabinet Package – MP3171		
Item	**Part No.**	**Qty**
StimLab™ Computer Cabinet	MP3167	1
StimLab™ Computer Cabinet Instruction Leaflet	MP3188	1

StimLab™ Local Station Package – MP3174		
Item	**Part No.**	**Qty**
StimLab™ Local Station	MP3114	1
StimLab™ Instruction Leaflet for Local Station	MP3178	1
Touch Screen Quick User Guide	MP3136	1
Stylus Pen and Holder	MP3133	1

StimLab™ Remote Touch Screen – MP3173		
Item	**Part No.**	**Qty**
StimLab™ Remote Station	MP3168	1
StimLab™ Instruction Leaflet for Remote Station	MP3177	1

8.4 StimLab™ Installation

8.4.1 Installation Description

The Micropace StimLab™ utilizes latest computer technology to implement a second remote touch screen without degradation of image on either screen and without practical limits on the distance. The device uses a high quality amplified video splitter, a video extender comprising of a balanced signal video sender unit and remote receiver, allowing standard CAT-5 cabling.

8.4.2 Installation of cables

Install StimLab Computer Cabinet, EPS320 Stimulus Generator Unit (SGU) and Local Touch Screen in the control room. All cables are externalized from the Cabinet so you will not need to open the Cabinet during installation. The Cabinet has three cable bundles exiting it, (i) Local Touch Screen Cables (ii) Remote Trunk Cable and (iii) SGU Cables. refer to the steps below and diagram on the next page.

1. First lay the Remote Trunk Cable under the floor or in the ceiling from the control room to the bedside with Stimulus Extension Cable MP3070 and SM-Box control cable MP3090 leaving exposed the Remote Touch Screen Socket (25pin circular in-line socket).
2. The Remote Trunk Cable is shipped pre-assembled into the Computer Cabinet so has to be pulled from the control room towards into the laboratory. If this is not possible, or if this cable needs replacement, refer to the section on the Computer Cabinet below on how to detach this cable from inside the cabinet. The remote connector requires a >50mm diameter channel to pass through.
3. Next connect the Local Touch Screen Cables - keyboard, local screen mains power, VGA cable and serial touch cable.
4. Next connect the SGU Cables – DC power cable and RS232 cable to the SGU.
5. Connect MP3059 mains cable to MP3107 Isolation Transformer and connect the transformer to mains.
6. At this point the Computer cabinet mains cable should be connected to the Isolation transformer. It is important that the mains lead is threaded through the Bracket MP3181 found in the Accessory box. The C14 connector should be inserted into one of the available sockets on the Isolation transformer. Using a screwdriver secure the bracket with the screws on either side of the transformer.

Warning: In order to comply with IEC60601-1 and avoid possibility of patient / operator shock from accidental connection of Stimulator computer parts directly to mains power, ensure that Isolation Transformer has Mains Cord Retaining Bracket MP3181 installed at all times

7. Connect the rest of the Stimulator as per the StimLab™ Installation Quick Guide – Four Channel SM-Box MP3086 to MP3070 and MP3090 and Stimulus outputs on the MP3089 to EP Recorder Stimulator Inputs using shrouded 2mm plugs.
8. If you have purchased a StimLab Mobile Stand MP3183 for the Remote Touch Screen, follow the installation instructions in that package on how to mount the Touch Screen.
9. In the EP Laboratory, place the Remote Touch Screen onto a suitable trolley or mount it on the Optional StimLab Mobile Stand MP3183 and connect it to the Remote Touch Screen Socket, usually located at the floor level.

8.5 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. Broadcasts selected protocol, raw stimulus intervals and pacing channel for inclusion in Stim Logs. No patient or diagnostic data are broadcasted.
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 for use when the Stimulator is located remotely to the patient, e.g. in a control room of the EP Lab and customer wants to locate SGU near patient and PC/LCD Screen in a control room.
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.

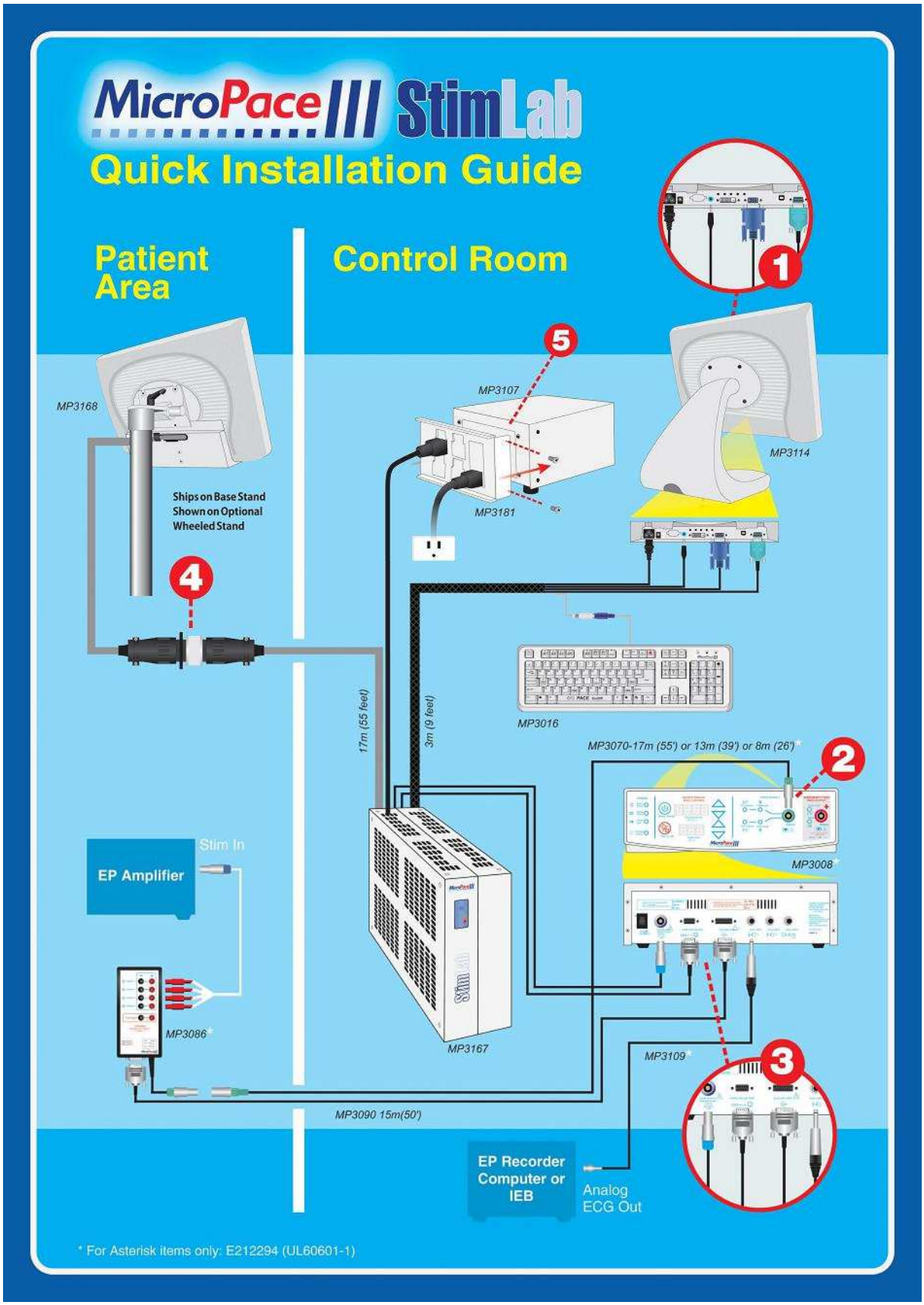


Figure 7 StimLab™ Installation Quick Guide

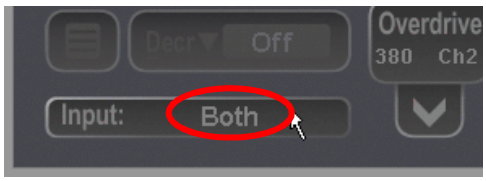
8.6 Using the StimLab™ Bedside Controller Features

The StimLab™ Stimulator and its Local Touch Screen is intended to be located in the control room and be connected to the Remote bedside Controller touch screen via trunk cabling placed under the floor or in the ceiling and joined with the Quick Connect 23 pin connector. The bedside Controller touch screen may be placed on a trolley using its supplied stand or mounted on an optional StimLab Mobile roll stand. When required, the Micropace bedside controller may be wheeled into the EP lab and hot-plugged to the Stimulator in using the Quick Connector, ready for use.

The physician then may observe and verify the Stimulator parameters set by the technician and if necessary adjust the Stimulator settings from the bedside.

8.6.1 Input Device Control

Pressing the Input button in left lower corner of display 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”.

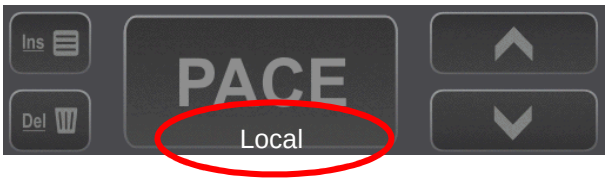
8.6.2 Local/Remote Indicator:

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



8.6.3 Touch Screen Availability Indication

(iv) “NO REMOTE Tch” - No remote Screen connected

(v) “NO LOCAL” - No local Screen connected( )

8.6.4 Always Active keys

The following keys and touch screen buttons remain always active on both interfaces for safety reasons:

Key / Button	Function
Esc key	Activates Keyboard, if it was disabled
F12	Starts Emergency Pacing and activates Keyboard if was disabled
F12: Emergency	Starts Emergency Pacing and activates Touch Screen if was disabled
Input:	Opens Input Device Menu for control of Keyboard, Local and Remote Station Touch screens

9 USING THE MICROPACE CARDIAC STIMULATORS

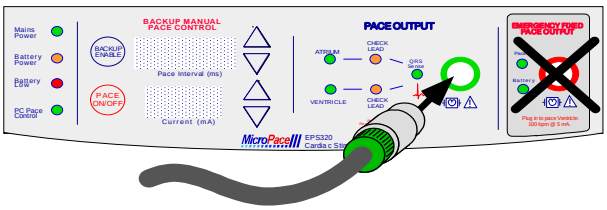
9.1 Connecting the Stimulus Connection Box

Connect the Stimulus Connection Box, MP3014 to the green PACE OUTPUT socket on the front panel of the Stimulus Generator Unit (see Figure 8). 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.

Figure 8 Insertion of Stimulus Connection Unit into the PACE OUTPUT socket.

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.

Where multiple ECG outputs are available –you may connect both the ECG1-INPUT and ECG2-INPUT via the 6.5mm Phone jacks on the rear panel of the Stimulus Generator Unit to ECG outputs on your EP Recording System. For optimal performance, ECG1-INPUT may be connected to the High RA IECG and ECG2-INPUT to the RV Apex IECG and you can access these using the ALT-1 and ALT-2 hotkeys respectively or ALT-X for automatic change with pace channel.

Note that any other electrically connected devices must be appropriately mains-isolated and exhibit CE marking in EU Countries.

SYNC-1 OUTPUT may optionally be connected to the EP recording Trigger input – the stimulator issues pulses on this line at end of stimulation sequences allowing the EP Recorder to move data from the live to the analysis screen

.

9.2 Switching on the system

Switch on the computer, the LCD screen and the Stimulus Generator Unit (the power switches are located on the LCD Display on its right edge, on the PC on the front panel and on the SGU on the rear panel). The main stimulator screen will appear automatically after boot-up. The computer software will then establish a serial RS232 link with the Stimulus Generator Unit. This may take a minute. If the software asks you if you want to reset or re-connect to the Stimulus Generator Unit, press 'y' for yes. Recheck that the Stimulus Generator Unit is switched on by the presence of a green (not yellow) light above the MAINS POWER label on the front panel.

9.3 Using the computer

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

Figure 9 allows the user to connect an USB or sound output device as well as providing the user with PC activity indicators.

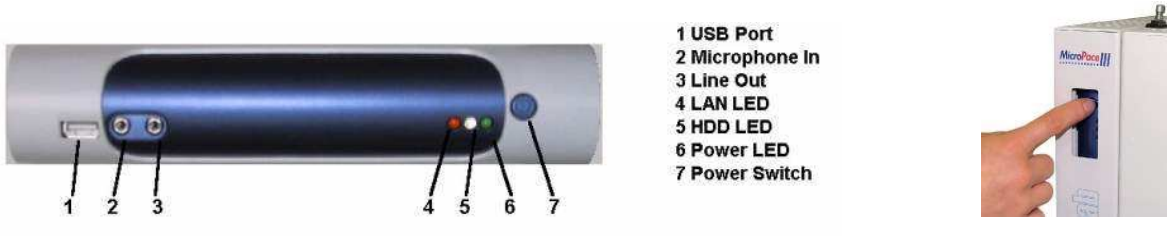


Figure 9 Computer front panel for EPS320B/BT (left) and StimLab / StimCor (right)

FEATURE	Explanation
1. USB Port:	Connection for USB device, such as the MP3101 External Floppy Disk Drive.
2. Microphone In:	Feature is not used – do not connect to this port.
3. Line Out:	Connection for MP3113 touch screen audio Input. Use Line out on rear of PC.
4. LAN LED:	Network activity indicator, not used.
5. HDD LED:	Indicates disk activity
6. Power LED:	Indicates computer is switched on
7. Power Switch:	Push to toggle Computer On/Off

Table 5 Computer Front Panel Explanations

9.4 Setting up the computer

a. Switch on (i) Isolation transformer, (ii) Bona PC (push front power 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 choose 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 Mains Stimulator Screen as below:

f. The Stimulator software will already be configured for your hardware setup – touch screen, four channels and one external ECG.

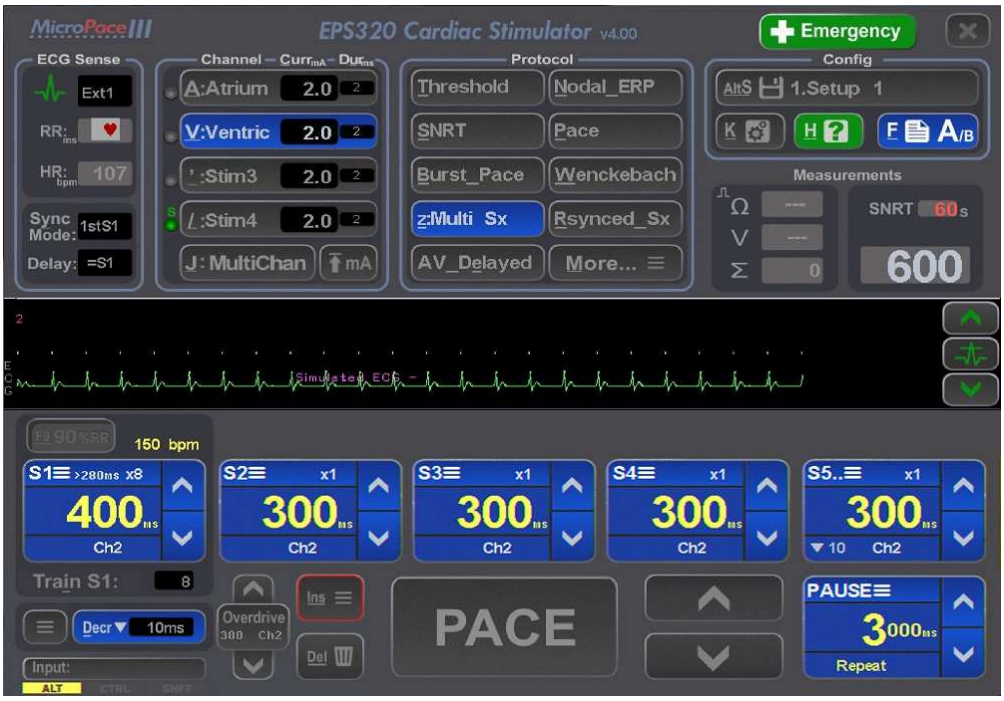


Figure 10 Main Stimulator Screen

10 VERIFYING THE SYSTEM

a. Verify Isolated Mains. Visually verify that all Micropace Stimulator components – PC, SGU, LCD Screen, are connected to a Medical Grade Mains Isolation Transformer e.g. MP3107.

b. Clean launch. Verify that SGU and Software launch without errors.

c. Test Pacing channels. Insert Stimulus Test LED, MP3058 (from the Installation Kit in the Accessories Box)) into the EP Recording Equipment's bedside catheter input modules (CIM's) - Block A. Configure the EP Recording Equipment to stimulate those outputs from the Chan 1 Atrial stimulation channel. Set current to 25mA and commence pacing into the Atrium - Stimulus Test LED should light with pacing (Yellow light indicates that the stimulus pulse is positive at the red connector and negative at the black one while Red light indicates the opposite or wrong polarity). Repeat pacing test for all four channels, using other 3 CIM Blocks. Similarly verify that Emergency Fixed Rate Pacing (red output socket) stimulates into Ventricle / Chan 2.

d. Verify ECG sensing. Connect ECG simulator to EP recorder surface leads, select one channel to sense from and verify that the Micropace Stimulator displays he ECG on the screen (if you don't have a simulator, create some noise on channel by touching the electrode).

e. Safety Acceptance. Finally, organize Biomedical engineering to perform acceptance test of the entire installed system according to the health facilities' procedure's.

f. Troubleshooting. If there are problems, refer to the troubleshooting guide in the Installation Manual and User Instruction Manual.

g. Make a record. Make a record of the verified installation and sign and date according to your company's quality system and file as required.

10.1 Train Customer

a. Customize Stimulator settings. Sit down with the responsible customer – chief technician or physician and set up various defaults for the Stimulator – default S1 values in protocols, minimum S1 and Sx values in Configuration menu. Save defaults into one or more of the Setups.

b. Demonstrate User Instruction Manual. Inform the electrophysiologist and technician of the safety features of the Stimulator and direct them to the relevant sections in the User Instruction Manual where safety warnings are listed.

c. Demonstrate Help feature, (hotkey 'h') wherever they are in the program, including diagrams. Explain Safety Diagram as an aid to safety items below. Help/ 6.Diagrams/ 6.Safety Guide is a useful diagram for this.

d. Demonstrate F12 Emergency Pacing key. While Stimulator is in normal PC control mode and in any protocol, press F12 / Red First Aid cross symbol on keyboard to demonstrate Emergency Pace protocol whereby both channels are immediately paced.

e. Manual Backup Pacing Mode - Demonstrate this safety mode (in cases of PC failure) by pressing the 'BACKUP ENABLE' button on the Stimulator) (or disconnecting Serial Cable MP3033A. Press 'PACE ON/OFF' button to pace. Adjust 'Interval' with up/down arrow buttons. Pacing is always into both channels. Hit [Enter] on the computer to re-enter PC Control mode.

f. Demonstrate Fixed Rate Emergency Pacing Mode. Instruct the User that should the SGU fail itself, they can use this feature. Connect Stimulus Test LED, MP3058 to Stimulator Output on the Ventricle / Chan 2 output and on the SGU front panel, remove the Stimulus Connection Box's green connector from the green Pace Output socket and insert it into the red Emergency Fixed Pace Output socket. The self-contained emergency circuit will commence pacing at 100 pulses per minute, 5mA and 2ms width (it detects presence of load resistance on the output and commences pacing automatically).

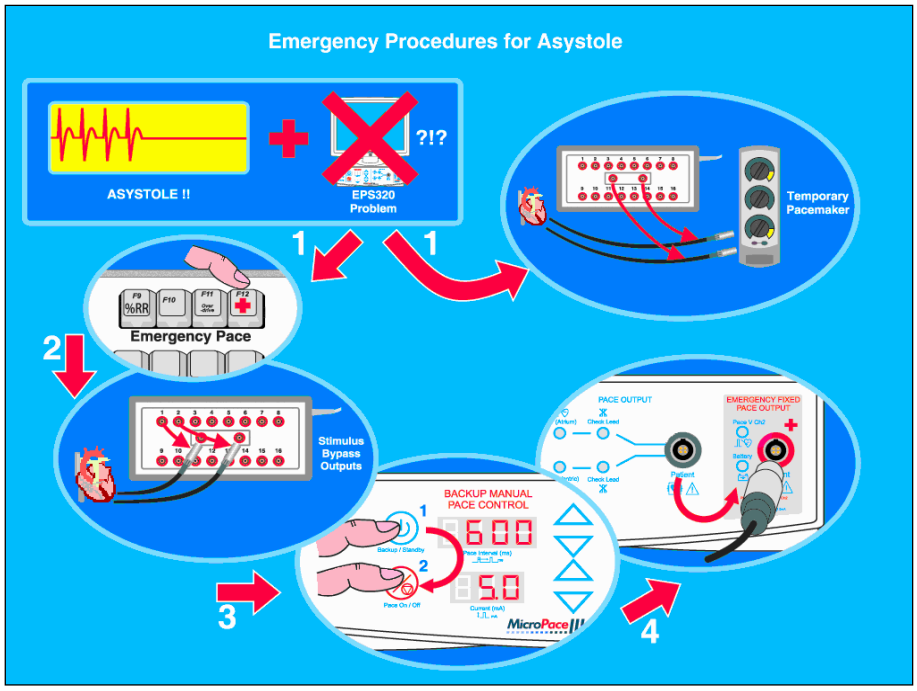


Figure 11 Demonstrate this safety mode

10.2 Make record

Make a record of the verified installation, date and sign and lodge record according to your company's quality system requirements. Installation is now finished.

10.3 Micropace Installation Checklist

The following checklist is to be performed after installation of the Micropace Stimulator and before first 'live' EP case. Any exceptions / failures must be signed off by Clinical specialist or engineer prior to use on patients.

Item	Test Method	Expected	Observed	P/F
1.Mains Isolation	Visually verify that all Micropace Stimulator components – PC, SGU, LCD Screen, are connected to a Medical Grade Mains Isolation Transformer e.g. MP3107, not wall socket.	All components plugged into Isolation Transformer.		
2.SGU POST	Power on SGU and observe all LED's during POST	All LED's light momentarily (except Emergency Fixed Rate Pace) and no errors appear on SGU display.		
3.Software Launches OK	Observe Stimulator Software launches without error messages.	SGU Main screen appears, no error messages		
4. Stimulation path & Polarity OK.	Connect Stimulator to EP Recorder, both configured for Ventricle/Chan 2 to stimulate at 20mA 10ms S1: 300ms; Insert Yellow/Red Test LED (MP3058) into breakout box where stimulus expected red to +ve. Start pacing and verify yellow LED lights with each pulse. If red LED lights then polarity is incorrect.	Yellow LED flashes with each stimulus.		
5.Emergency Fixed Rate Pacing OK	With a Test LED across the Ventricle/Chan2 output s in 4. above, change over stimulus cable connection to the SGU from Pace Output green socket) to Emergency Fixed Rate Pacing Output (red socket). Observe pacing. Restore stimulus cable to green 'Stimulus Output' connector.	Pacing sound is emitted and yellow LED lights at approx. 100 ± 20% ppm. Test LED pulses light. 'Battery' indicator lights after about 4s.		
6.ECG Visible	Connect ECG simulator to one channel on the EP Recorder, select it for ECG sensing and verify that Stimulator displays ECG on its screen. If no ECG simulator available, connect one pin of Test LED and get someone to touch the other pin to create an unbalanced noise source.	ECG / noise is seen on Stimulator screen.		
7. Touch screens active	Verify that both Central and Bedside touch screens function by starting and stopping Emergency pacing	Pacing starts on pressing and holding Emergency button for 2 seconds and stops with Pace On/Off.		
8 Biomed Engineering approval	Health facility's Biomedical Engineering Dept. is generally required to test and accept the installed system for electrical safety; ensure that this has been done.	Biomed Engineering acceptance verified.		

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 12 shows the main hot keys.

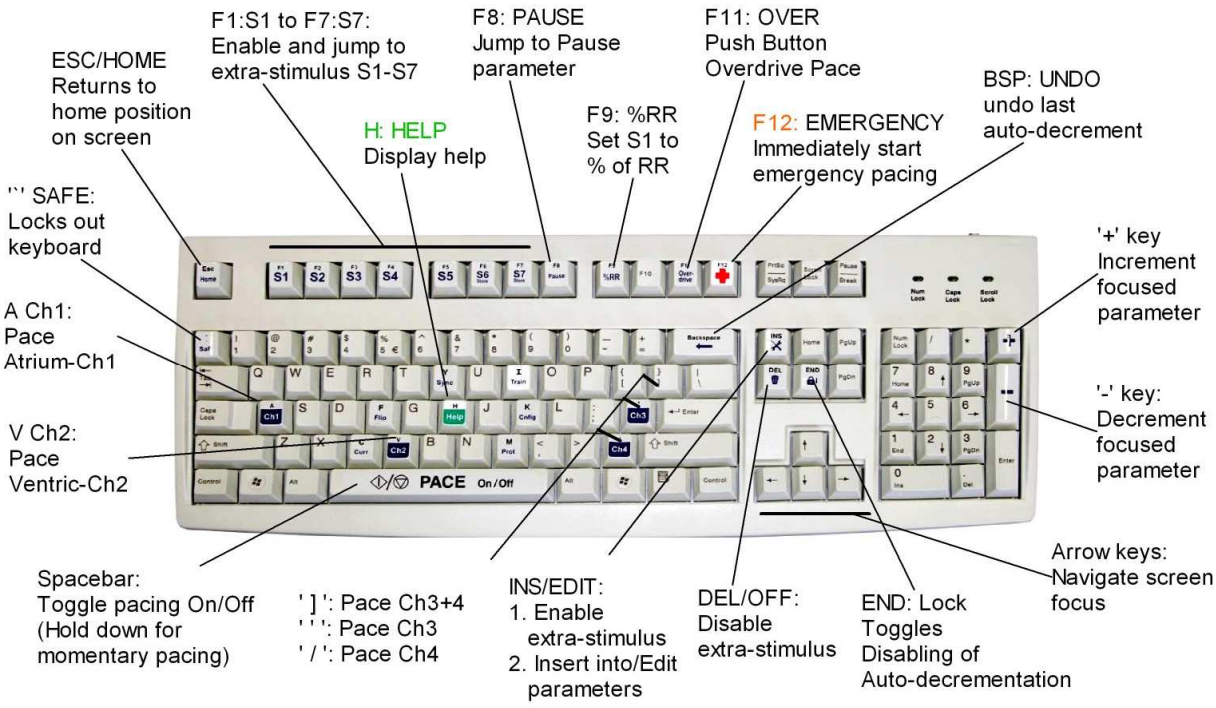


Figure 12 Keyboard Layout – for reference only

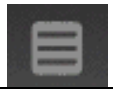
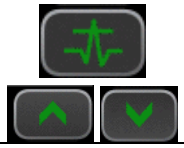
The Touch Screen is a 15” touch LCD display, which works with software Ver 3.21, to make existing Stimulator menus on the screen controllable by touch.

- You may use your finger, gloved finger or a soft stylus, such as the back of a plastic pen.
- The user may focus screen parameter 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.

Figure 13 Touch Screen

- 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.

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.
	Spacebar	Toggles Pacing On/Off, sustained touch – push to pace.
	INS / EDIT	Enables Sx, edits focused parameters
	DEL	Disables Sx, modifies focused parameters
	**+ / -**	Small Increment / decrement, e.g. S1 by 10ms
	F12- Emergency	Starts emergency pacing into both channels. Prolonged press of 0.35 sec required to activate.
	Q / Esc	Exits menu / application
	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 +/-
	90% (F9)	Make S1 90% of average RR, or whatever value programmed. The Percent value now adjustable by Config Var 9 ‘F9 %RR Percentage’’

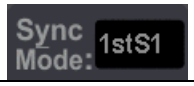
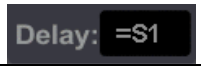
Touch Button / Zone	Keyboard hot key	Function
	F11	One touch Overdrive Burst Pace. Prolonged press of 0.35 sec required to start pacing 1st time and again whenever button left idle for 20 sec; button remains green color when armed for immediate pacing. "Ch2" indicates which channel will be paced and 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.
	None	Toggles control between Keyboard only, Touch only and Both
	None	Measured Pacing Results **Ω :** Pacing Impedance in Ohms **V :** Pacing Voltage in Volts **∑ :** Number of pacing stimuli generated
	Alt-S/Alt-R	Save / Restore settings
	K	Configure Stimulator
	H	Help
	F	Flip / change between Stimulator Page A and Page B
	None	R-R Interval in ms
	None	Heart Rate in beats per minute
	Y	Synchronize pacing to ECG
	None	Delay from Sync to S1
	D	Decrements S values
	I	Set number of pacing stimuli in one Train
	Ctrl-Ins/ Ctrl-Del	Maximum Current
	None	Stimulation delivered
	Alt / Ctrl / Shift	Key pressed

Table 6 Touch buttons, touch zones and their functions

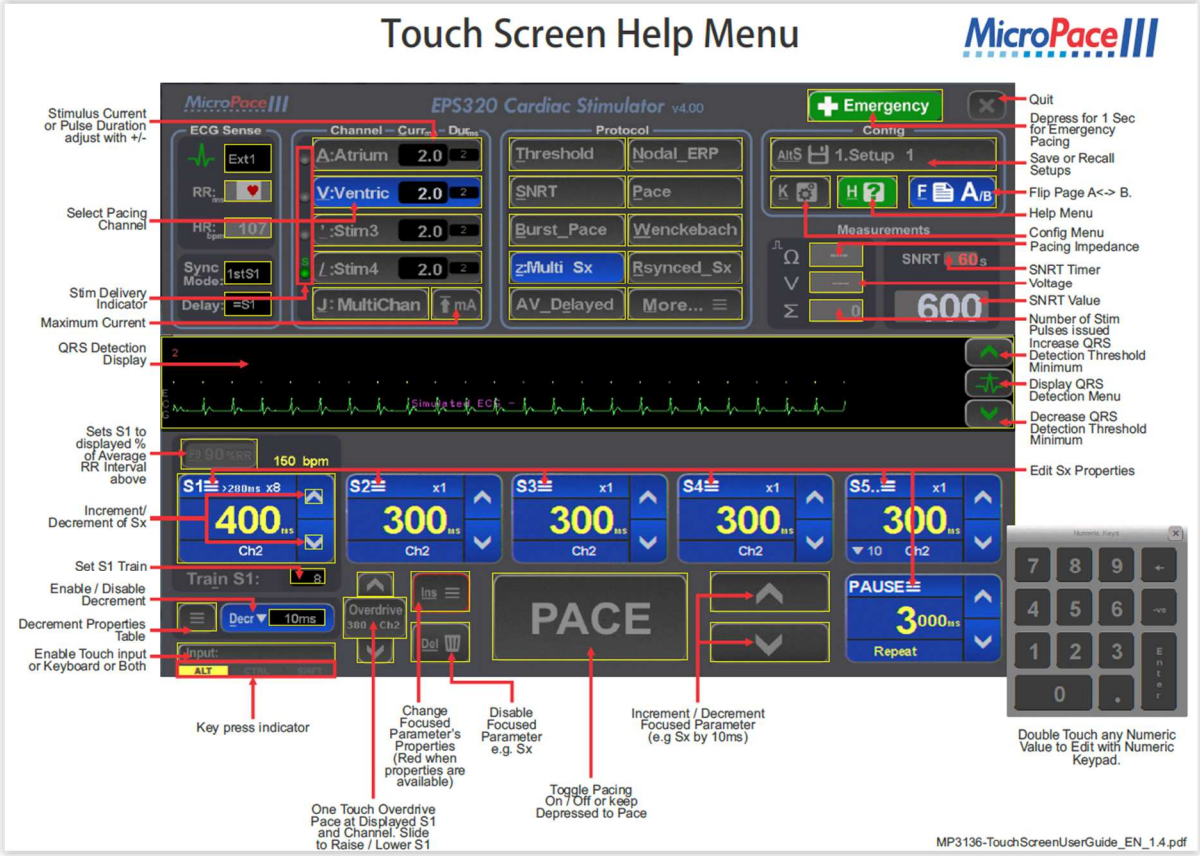


Figure 14 Summary layout of functions of Touch Buttons / Zones

11.1.1 Numeric Keypad & Mouse control

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.

For those who prefer a mouse interface instead of the touch screen, an optional validated pointer mouse is available from Micropace on request.

12 USING THE STIMULATOR SOFTWARE

12.1 Help Function

The user is encouraged to make use of the extensive context-sensitive help. This is available for every parameter and every protocol by pressing the 'H' hotkey (you must focus on the parameter first, either by its hotkey or using arrow keys).

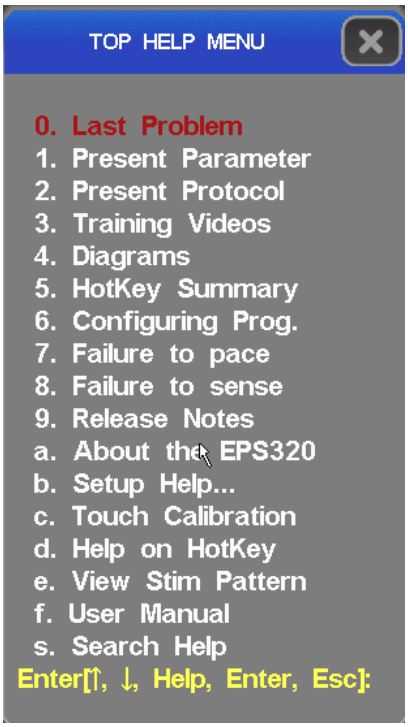


Figure 15 Help menu

A list of all hotkeys with explanations is also available directly by pressing hotkey 'Alt-M'.

12.2 Training Videos

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

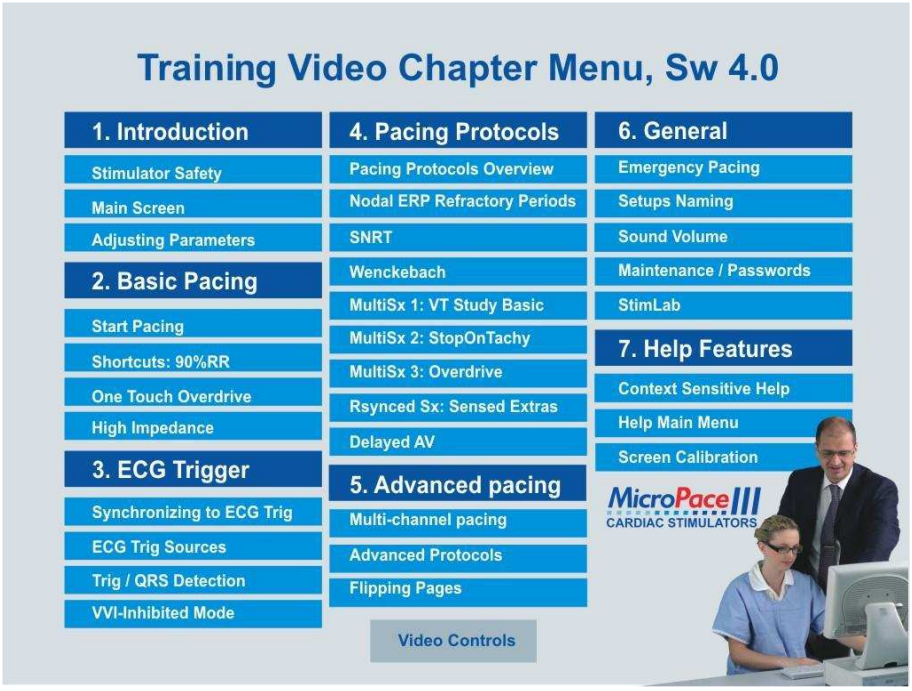


Figure 16 Training Video Menu (English)

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 17. 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.

The STIMULUS parameter menu, the stimulation PROTOCOL menu and the PACE_SITE menu in the top half of the screen are menus used to set the corresponding parameters. The PACE_STATUS display and the ECG DISPLAY BAR in the middle of the screen show the progress of the stimulation sequence.

The Optional Touch Screen configuration features Touch Buttons at bottom center of screen, duplicating the action of some hot keys (see section on Touch Screen above).

12.5 Pacing Parameters

To set the parameters in Figure 17, 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. Use the Esc key to return screen focus to its Home position - usually the highest activated extra-stimulus parameter.

12.6 Basic Pacing

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

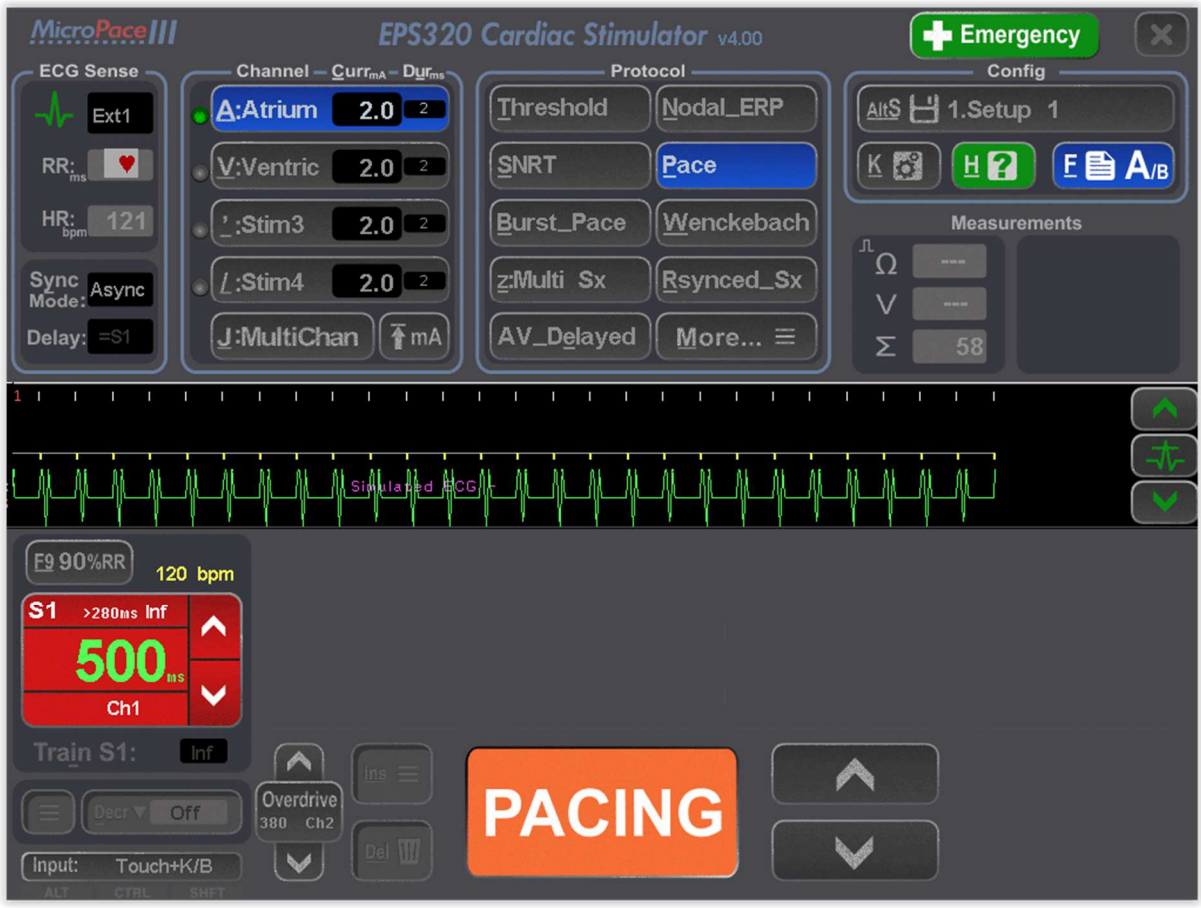


Figure 17 Stimulator User Interface screen set to PACE protocol.

12.7 Overview of the Stimulator Software

Threshold Protocol. In a typical EP study, the stimulus threshold will be initially determined. Press 'T' to select the THRESHOLD protocol and select the desired pacing site by pressing 'A' or 'V' if different from the default. Next, start pacing by pressing the [Spacebar]; output current will be automatically decremented. You will need to stop pacing when loss of capture occurs and a suggested new default current will be displayed (twice threshold current, and > 1.0 mA). Adjust the current at any time by pressing 'C' for Current and enter the new value.

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). The ECG trace and symbols for detected P/QRS complexes are shown below this; any triggering P/QRS is marked with a longer symbol.

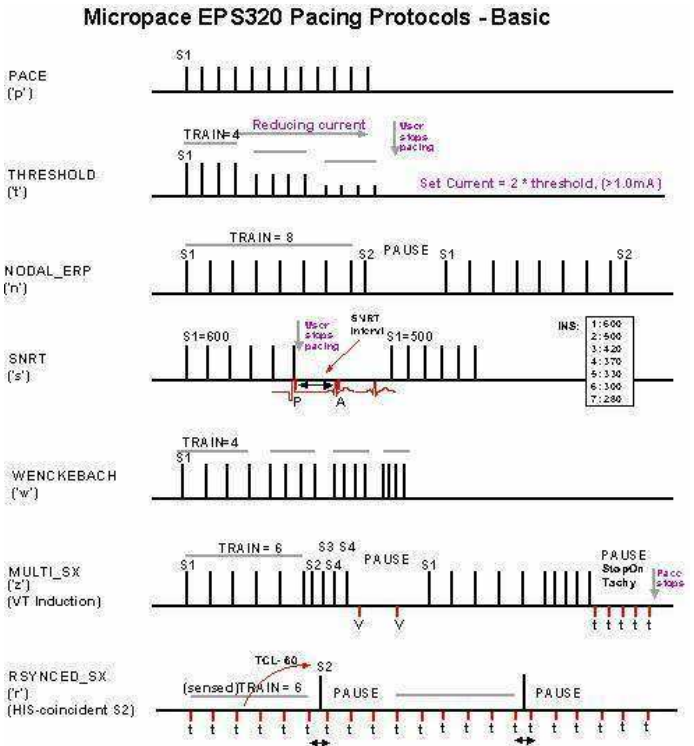


Figure 18 Stimulation patterns in basic pacing protocols

Nodal_ERP and Multi_SX Protocols. The NODAL_ERP protocol features 3 extra-stimuli for refractory measurements, with adaptive auto-decrementation 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 18 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'. The pacing site and the final S1 value will be remembered on the next call to OVERDRIVE. The ATP_AICD protocol (hotkey 'L') provides overdrive pacing protocols similar to those used in Implantable Defibrillators (AICD's). ATP may be delivered at a preset percentage of the sensed VT cycle length set by S2 or at a fixed starting interval in ms set by S1. ATP train length may be set by the TRAIN variable and automatic decrementation of S1 between drive trains, may be set by the AUTO_DECREMENT parameter. A minimum S1 specific to this algorithm and intra-train decrementation may be programmed from the Config menu (hotkey 'K').

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. P/QRS detection has automatic gain and needs no adjustment. Amplitude of the external ECG may be also altered by adjusting the amplitude of the output signal from your EPS Recording equipment. The

AUTO_TIP automatic site senses pacing catheter-tip IECG from whichever channel is being stimulated.

Sync Trigger output interfaces. Trigger / Sync output for your EPS Recording equipment review screen is provided on the 8th train pulse in the NODAL_ERP and the MULTI_SX protocol, the first P/QRS-coupled extra-stimulus in Rsynced_Sx protocol and when pacing is stopped in SNRT, BURST_PACE, WENCKEBACH and ATP_AICD protocols. This may be adjusted in the Config Service menu.

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.

Loading Stimulator Defaults. When loading Protocol setup memory, the defaults loaded will be for all protocols and not just the protocol currently selected.

12.8 Stimulation Parameters

The following stimulation parameters may be used to control the basic stimulus train characteristics:

12.8.1 S1 Parameter

Basic stimulation interval.

S1 is decremented automatically in WENKEBACH or BURST_PACE protocols by Screen Parameter 'Decrement' in ms.

Safety lower limits may be set in the Config Var_1. This lower limit is displayed at the bottom of the S1 parameter. Some protocols such as BURST_PACE and OVERDRIVE_PACE have their own lower safety limit - Config Var_2.

Pacing is toggled on and off by hitting SPACEBAR key. Prolonged press of the SPACEBAR key maintains pacing only while the key is pressed.

Values below 230 ms are subject to once only warning of possible induction of FLUTTER; values below 100 ms are subject to a recurrent warning of FIBRILLATION. Both warnings are configurable by Config Service Var_40.

In protocols:	All except R_SYNCED_SX	
Altered by	3 or 4 digits:	sets value
	+/-:	Changes value by 10ms
	Ctrl +/-:	Changes value by 100ms
	Alt- +/-:	Changes value by 5ms.
Values:	30-9990:	S1 value in ms, depending on protocol.

12.8.2 S1 Train

Number of stimuli in drive train or between auto-decrementation of S1.

In protocols:	NODAL_ERP & MULTI_SX:	Number of stimuli in drive train.
	BURST_PACE:	Pacing terminates after this many stimuli.
	THRESHOLD:	Current decrements every so many stimuli.
	WENCKEBACH:	S1 decrements every so many stimuli.
	RSYNCED_SX:	No. of sensed P/QRS complexes before issuing of extra-stimuli.
	PACED_S2:	Number of S1 before interpolated S2/S3 are issued.
Altered by	Numeric Keys:	Sets train value
	+/-:	Increment / decrement by 1

	DEL:	Sets to infinite, INF
Values:	0 to 99:	Number of stimuli
	INF :	Unlimited stimuli

12.8.3 Decrement

Automatic decrementing (or incrementing) of auto-decrement-able parameter in each protocol. Values are entered with a single digit followed by [Enter] or by two digits alone.

In protocols:	All except PACE and DELAYED_AV.	
	NODAL_ERP & MULTI_SX:	Decrements highest enabled Sx
	BURST_PACE:	Intra-burst S1 decrement
	THRESHOLD:	Decrements current
	WENCKEBACH:	Adaptively decrements S1
	RSYNCED_SX:	Decrements highest enabled Sx
	PACED_S2:	Decrements highest enabled Sx
Altered by	+/-:	Changes by 5ms, except THRESHOLD where flips decrement to increment.
	DEL:	Turns Off decrementation.
	INS:	Turns On decrementation or enables decrement by Table (Tbl).
	Auto Lock / Alt-L:	Lock Off all decrementation in all protocols
	Alt-U:	Negates Decrement value causing incrementation
Values:	-99 to -1 :	Increments
	Off :	No decrementation or incrementation
	1 to 99 :	Decrements
	Tbl :	Use Pre-programmed table of values
	-1~mA, 1~mA :	Increase / decrease current in Threshold
	Lock :	Lock decrementation temporarily

Negative Decrement values, set by '-' key or Alt-U, cause incrementation of extra-stimuli in the NODAL_ERP, MULTI_SX, RSYNCED_SX protocols.

If the Operator manually adjusts the extra-stimulus between trains, auto-decrementation is suppressed in the above protocols for one train.

The Tbl value, set by INS, uses a table of programmable values.
Refer to Help on Decrement in specific protocols.

12.8.4 S2-S7 Parameter

Extra-stimuli displaying the coupling interval in ms.

In protocols:	NODAL_ERP, MULTI_SX, R_SYNCED_SX, PACED_EXTRAS	
Altered by	3 or 4 digits:	Sets Sx value
	+/-:	Changes value by 10ms
	Ctrl +/-:	Changes value by 100ms
	Alt- +/-:	Changes value by 5ms.
	INS:	Enables Sx and all lower Sx
	DEL:	Disables Sx and all higher Sx
	Ctrl-INS:	Unmasks focused Sx - Masked Sx's are not delivered
	Ctrl-DEL:	Masks focused Sx - Masked Sx's are not delivered
	Alt-D:	Auto-decrements focused Sx
	Function key double strike: increments corresponding Sx by 10ms	
Values:	0-9990:	Sx value in ms, depending on protocol.

Value e.g.: 80 - 9990ms (Lower limit set by Config Var_3).

S2 to S7 may be auto-decremented by Decrement Screen Parameter in the following protocols:

(i) NODAL_ERP (S2-S4)

(ii) MULTI_SX protocol

(iii) RSYNCED_SX protocol

S2-S7 auto-decrementation may be programmed to be in steps of 50, 20 and 10 depending on S1 value according to a Table, enabled by Config Var_11.

S2-S7 may be auto-incremented by making Decrement negative by decrementing with '-' key to -ve values or with the ALT-U hotkey.

Auto-decrementation is normally applied to the highest enabled Sx. Auto-decrementation may however be redirected to any one Sx by focusing it and pressing Alt-D.

Quickly increment any Sx by 10ms by a double strike of the corresponding Function key – F4 key hit twice increments S4 without the Sx needing to be focused.

S7 Parameter will not be accessible when Touch Screen is enabled.

12.8.5 Pause Parameter

Control of repetition and the duration of Pause between repeated sequences of stimulation.

In protocols:	NODAL_ERP, MULTI_SX, RSYNCED_SX, PACED_EXTRAS, ATP_AICD	
Altered by	4 digits:	Sets Sx value
	+/-:	Changes value by 1000ms, (100 in RSYNCED_SX /XRS_SX)
	Ctrl +/-:	Changes StopOnTachy detect interval if enabled
	Alt- +/-:	Changes value by 500 ms.
	INS / EDIT:	Opens Pause Mode Selection Menu
Values:	500-9990	Pause, (100- 9990 in RSYNCED_SX protocol)
	Repeat :	Repetition of drive train sequence after PAUSE interval
	Repeat/StopOnTachy :	Conditional repetition of drive train
	No-Repeat :	No repetition of drive train sequence
	Pause=S1 :	Repeat without pause

StopOnTachy PAUSE mode (StopOn < xxx):

Pacing stops following a stimulation train sequence if tachycardia is detected within the PAUSE interval with cycle length less than the indicated StopOnTachy value (in ms). Tachycardia detection is entirely dependent on general sensed ECG quality as well as ECG quality during tachycardia, which may have a different axis to that of, paced or sinus rhythm, or may deteriorate due to catheter movement.

StopOnTachy threshold interval may be changed with Ctrl+/- keys; default is 390ms (defined by ConfigVar_22-Tachy detect interval). Note that tachycardia is not sensed during pacing.

In the StopOnTachy PAUSE mode, when no tachycardia is detected within the PAUSE interval, stimulation repeats after the set PAUSE interval plus 500ms.

If last sensed RR interval falls outside the StopOnTachy threshold, the Stimulator re-confirms termination of tachycardia for 1.5 s while displaying a note "Re-confirm".

P/QRS complexes sensed as tachycardia are market with a purple 't' symbol under the complex, to aid Operator in detecting under or over-sensing. Use QRS Detect window to adjust P/QRS detection criteria if necessary (hotkey Alt-q).

12.8.6 Channel - Current - Duration

The Micropace Stimulator can help automate some tasks such as ERP and SNRT measurements if the Operator uses Ch1 for the Atrium and Ch2 for the Ventricle - channels are named so by default to facilitate this.

When stimulating other sites, Operator can refer directly to Ch1 to Ch4, or can attach custom names to these channels (see below).

Applicable hotkeys: A, V, ‘, /, J, INS

Pacing site is by default automatically selected for some Protocols such as Atrium / Ch1 for the SNRT protocol. This may be prevented by changing Config Service Var_14-En_Universal_pace_site.

Menu selections include:

ATRIUM-Ch1:	Outputs to Ch1 output. For optimum Stimulator automation, this channel is typically used to stimulate the high right atrium, or the more proximal pacing site in the cardiac conduction tree. E.g. the SNRT protocol defaults to this channel.
VENTR- Ch2:	Outputs to Ch2 output. For optimum Stimulator automation, use this channel to stimulate the ventricle, or the more distal cardiac site.
STIM 3- Ch3:	General purpose channel. It shares the current generating circuit with Ch1, so the stimulator can’t stimulate both simultaneously. If the Stimulus Multiplexer Box (SM-Box) is installed, then stimulus appears on Output Chan3. If StimLink™ is installed with a communicating recording system, then the stimulator sends a command to recording system to switch stimulating channel in the recorder to Chan3. If neither of the above 4 channel accessories is installed, then stimulus appears on Chan1 output.
STIM 4- Ch4:	General purpose channel. It shares the current generating circuit with Ch2, so Operator cannot stimulate both at once. With four channel accessories, output is re-directed to Chan4, otherwise stimulus appears on Chan2 output.
MultyChan:	Programmable simultaneous Ch1 to Ch4 stimulation. This Joined Channel Connection Menu allows independent connection of S1 to S7 pulses into either one or two channels. The default menu setup is for S1 to pace both Atrium and Ventricle and extra-stimuli to pace only ventricle. This is useful for MULTI_SX / VT-induction studies in patients with VA block; whereby combined A and V pacing for S1 prevents corruption of drive-train by captured or fused asynchronous sinus beats.

Channel renaming:

Operator can rename channels in the Pace_Site menu by focusing the menu (Current) with arrow keys and pressing INS key. This displays a menu of 5 names; Operator can select the name to change with arrow keys and press INS again and type in new name. The new name is displayed only in the Pace Site menu; it is stored permanently.

Roving pacing catheter:

If you stimulate with only one catheter, moving it between Atrium and Ventricle, set Config Service Var_14-‘En Universal Pace Site' to 3. to redirect all output to Ch1/Atrium channel.

12.8.7 Current

The stimulus Current amplitude to be delivered.

In Protocols	All	
Altered by keys:	Numeric Keys:	Current value in mA
	Keypad +/- :	[change value in above pseudo-logarithmic steps]
	CTRL+/- :	2mA change
	ALT+/- :	0.1mA change
	Top Row +/-	0.1mA change

	CTRL-INS :	Forces current to 20 mA (for His stimulation)
	CTRL-DEL :	Restores current from 20mA to previous value.
Values:	0.1, 0.2, 0.3... 4.8, 5 ,6 ,7...10,15...25 mA.	

An attempt to change current by > 10mA with numerals issues a Warning. Use Ctrl INS/DEL to boost Current to 20mA and restore.

Failure to deliver current causes the following:

- Check Lead LED to flash on the SGU
- A lower pitched pace sound
- 'L' shaped pace symbol on screen and
- High Atrial/Ventricle Impedance Warning text.

12.8.8 Duration

Duration of Stimulus pulse in ms.

In Protocols	All	
Altered by keys:	Numeric Keys:	Duration set in ms
	+/-:	Increment / decrement by 5ms
Values:	0.5,1,1.5,... 9.5, 10	Duration in ms.

12.9 ECG Sense

12.9.1 ECG Sense Site

ECG input is used for the following purposes:

- Synchronizing onset of Pace train to the patient's P/QRS (if you have SYNC turned to P/Q for the protocol being used).
- Measuring SNRT value in the SNRT protocol (you need Atrial sensing)
- StopOnTachy feature.

Four ECG Inputs are available from the SENSE_SITE MENU:

Ext1:	[Alt-1] - Senses from 'ECG-1 Input' on the rear panel of the SGU
Ch1/3:	[Alt-a] - Senses from the Atrial channel pacing electrodes (no need for external ECG)
Ch2/4:	[Alt-v] - Senses from the Ventricular channel pacing electrodes (no need for external ECG)
AUTO	[Alt-i] - Senses from currently selected Pacing Site catheter- tip

Use Alt_Q (QRS Detect Menu) to adjust the P/QRS detection parameters if required.

Recommended setup:

If using only one external ECG sensing channel, then set the Sense Site to Ext1.

If no external ECG signal is available, then use the Auto Catheter-Tip sensing, hot key Alt-I.

12.9.2 Sync Mode

Sets type of pacing - Asynchronous or Inhibited.

In protocols:	All

Altered by Values:	+/- and INS / DEL:	Scroll through possible values.
	Asyn:	Pacing will commence immediately and not synchronized to ECG
	1st S1:	Pacing starts after next sensed P/QRS
	Inhbited:	INHIBITED pacing corresponding to the VVI / AAI pacing.

There is no hotkey for this parameter; Operator must focus on the parameter with the 'up' arrow keys and adjust using +/- keys.

If over-sensing occurs, stimulation may be inhibited permanently; the protocol has no timeout on commencing stimulation.

12.9.3 QRS Detect Menu

Use this menu, shown below, to adjust P/QRS detection. If detection is not optimal, select the Presets for IECG or surface ECG or for tachycardia according to your circumstances. You can store a customised set of parameters using Store Custom command. Set any Preset as the default on program launch by specifying its number into Config Var 30 Soft QRS Detect Setup.

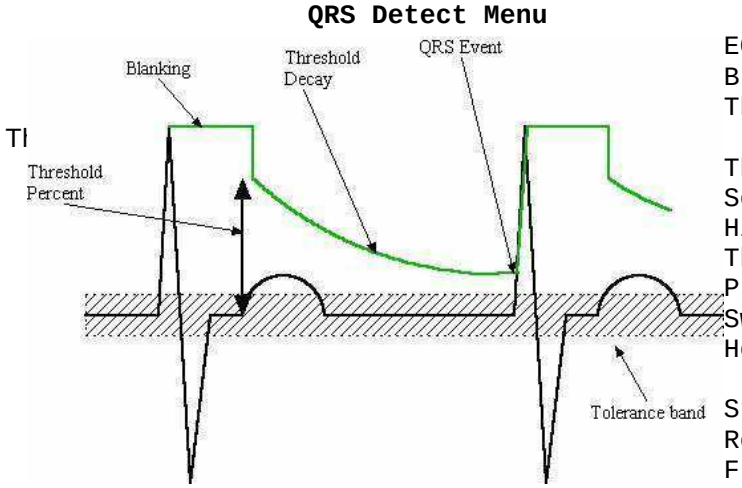


Figure 19 QRS Detect Menu

QRS sensing can be set to +ve, –ve or Biphasic from this menu, controlled by **(Thr. +:0 -:1 ±:2)**

QRS sensing channel can be set using Sense: item in the list

12.10 Pace Status

12.10.1 RR Measurement

Beat-to-beat RR interval and average (exponential filter with weighting against outlier values) RR intervals are displayed.

12.10.2 Impedance measurement

Pacing circuit impedance is measured with each pulse to aid the operator in determining the integrity of the pacing circuit. Values below 500 Ohms suggest a short in the pacing circuit, while values above 2000 Ohms suggest high impedance. It is not displayed for stimulation currents below 0.6 mA. The measured value includes variable impedances internal to the Stimulator and the accuracy is limited; it

is not a measure of the 'lead impedance' used in permanent pacemaker implantation and should not be used as such.

12.10.3 ECG Display Bar

During pacing, the ECG DISPLAY BAR will display a Stimulus Symbols for stimulus in each channel (short vertical lines for S1, longer for S2-S7). The sensed ECG trace and detected P/QRS symbols are shown below this. Minimum threshold level for the QRS sense trigger can also be changed from the main screen using the up & down arrows on the Right edge of the trace (QRS Detect Sensitivity in Figure 17. The level will be briefly indicated by a green horizontal line.

12.11 Pacing Protocols

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

12.11.1 Protocol Selection & Renaming

Favorite 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 INS/EDIT key.

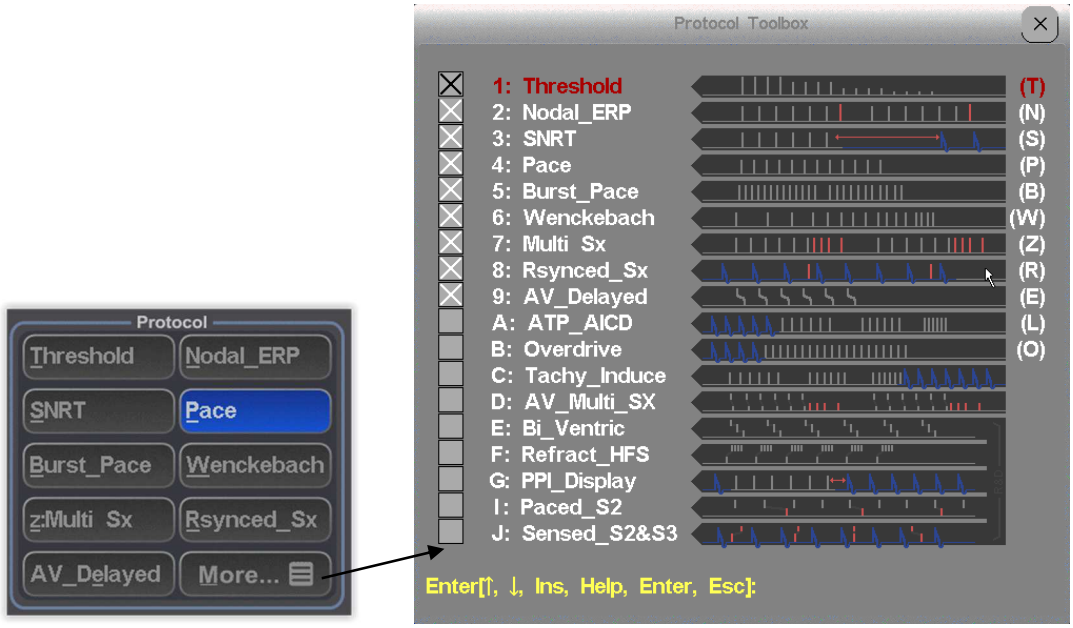
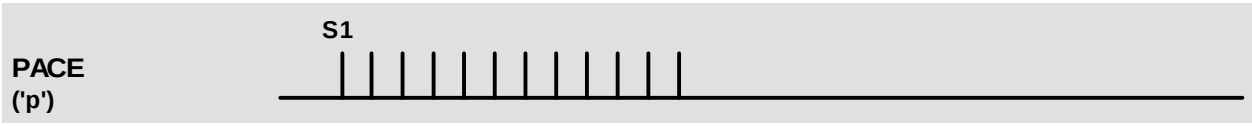


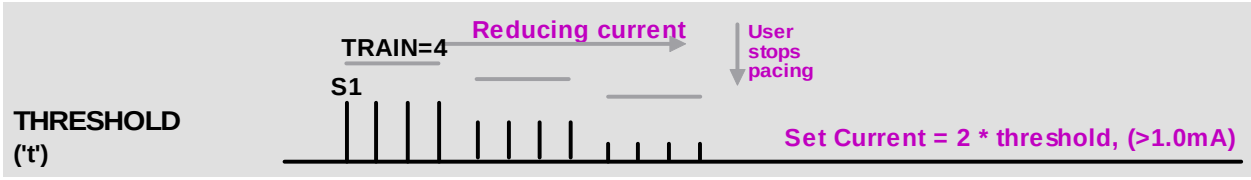
Figure 20 Protocol Toolbox

12.11.2 Pace Protocols



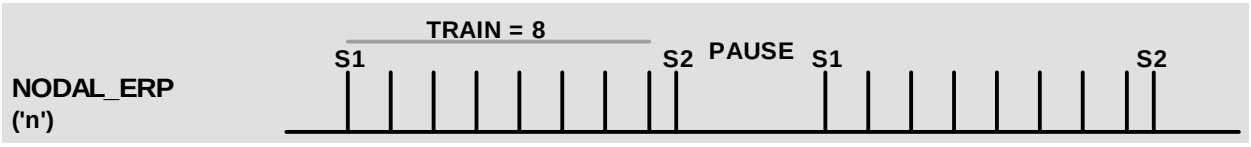
Select the PACE protocol to pace at a fixed interval set by S1 into selected pacing site.

12.11.3 Threshold Protocol



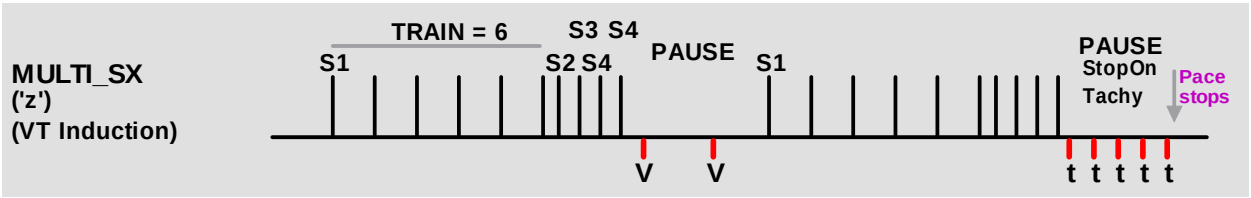
The THRESHOLD protocol helps to determine the pacing threshold by continuously decreasing or increasing the pacing Current amplitude; the Operator needs to stop pacing when capture is lost, and accept or modify a displayed automatically calculated new default current (twice threshold current, and > 1.0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

12.11.4 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).

12.11.5 Multi_Sx Protocol

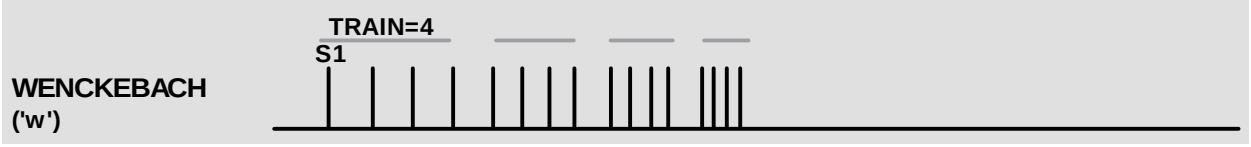


The MULTI_SX protocol provides up to 6 auto-decremented extra-stimuli primarily for programmed ventricular stimulation. A warning message “Defibrillator Ready?” appears on entry to protocol if pacing into Ventricle, its appearance is configurable by your distributor. In both above protocols, manual adjustment 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:

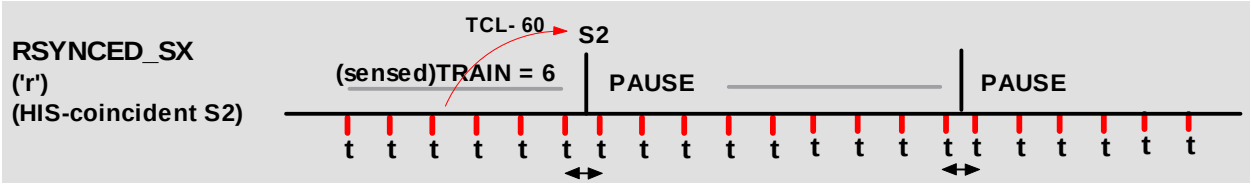
- ❑ Enable first S1 Trigger from Sensed P/R or no trigger.
- ❑ Enable AV delay for S1.
- ❑ Set S1 AV delay time in ms.
- ❑ Set individual S1 Train number control. The train value is displayed on the bottom of the Sx button.
- ❑ Enable individual S2- S7 auto-decrement for this Sx according to the common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

12.11.6 Wenckebach Protocol



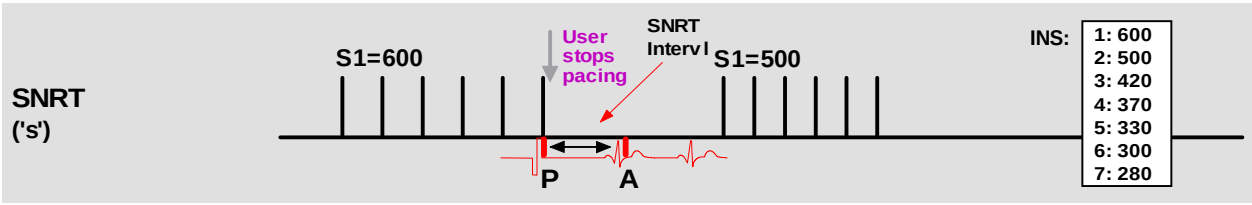
The WENCKEBACH protocol continuously decrements S1. Decrementation may be optionally terminated by manual adjustment of S1 (configurable by your distributor); in software versions 3.19.59 or earlier, decrementation was also paused by continuous press of the [Spacebar].

12.11.7 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.

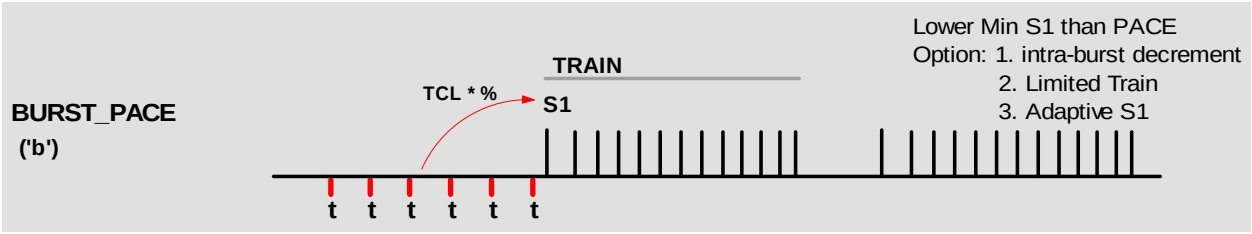
12.11.8 SNRT* Protocol



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 DECREMENT or S1 parameters while in the SNRT protocol. Alternatively, the DECREMENT variable may be used to decrement the S1 (customised by your distributor).

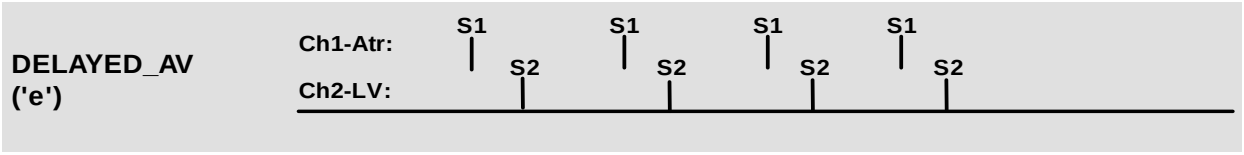
*Note: SNRT value calculation may not function correctly when sensing IECG from the catheter-tip; use external ECG sensing to obtain SNRT calculation by the EPS320 Stimulator.

12.11.9 Burst_Pace Protocol



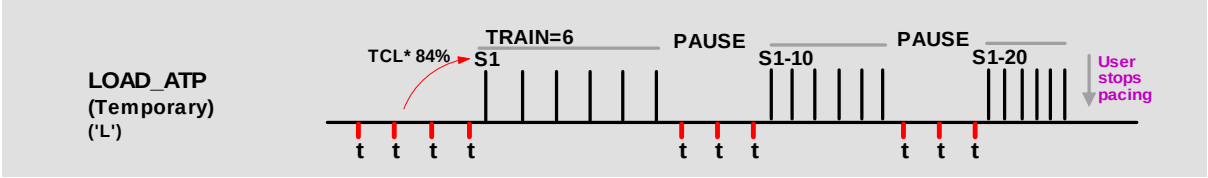
BURST_PACE protocol allows more rapid pacing with S1 values as low as 30ms (subject to its own Config Var-2 ‘Lower limit for S1 in Burst’). Configuration Variable 7 can be used to redirect Burst Pace to Overdrive Burst pace whenever burst pace is engaged.

12.11.10 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.

12.11.11 Overdrive Pace and ATP Protocols



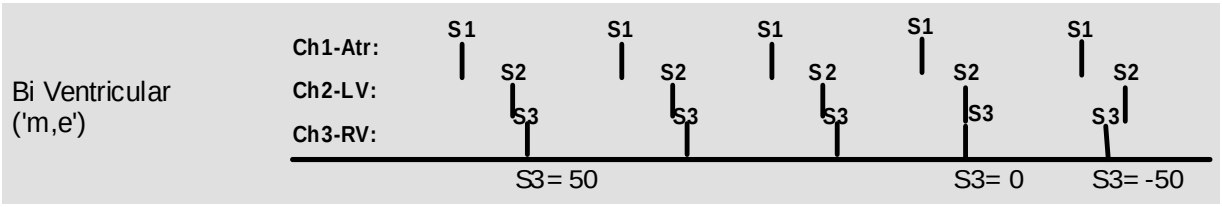
The ATP_AICD – anti-tachycardia pacing, protocol (hotkey 'L') provides overdrive pacing protocols similar to those used in Implantable Defibrillators (AICD's). ATP may be delivered at a preset percentage of the sensed VT cycle length set by S2, or at a fixed starting cycle length in ms set by S1;

either value is adjustable by the Operator prior to commencement of pacing. The ATP sequence length may be set by the TRAIN variable and automatic decrementation of S1 between drive sequences may be set by the AUTO_DECREMENT parameter. A minimum S1 specific to this algorithm and intra-train S1 decrementation may be set by Config Var-4 and Config Var-19 in the Configuration Menu (hotkey 'K') respectively.

12.11.12 Specialised Protocols

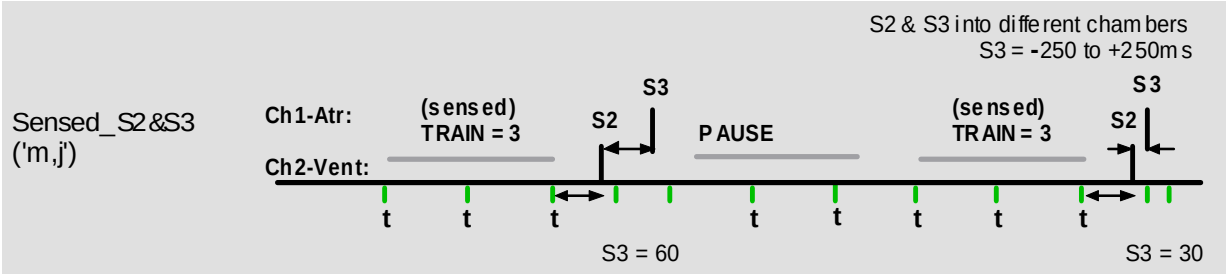
The following specialised protocols are available from the Procedure Menu (‘m’). They are self-explanatory.

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

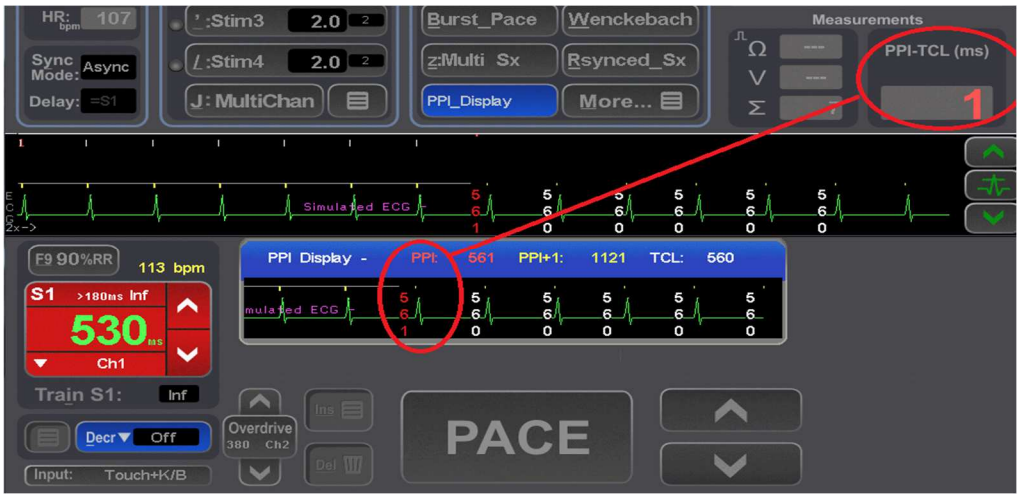


Paced S2. S2 into a different channel to S1 is interpolated between S1stimuli. S2 may be 0 or –ve, meaning it coincides or preceedes the last S1:

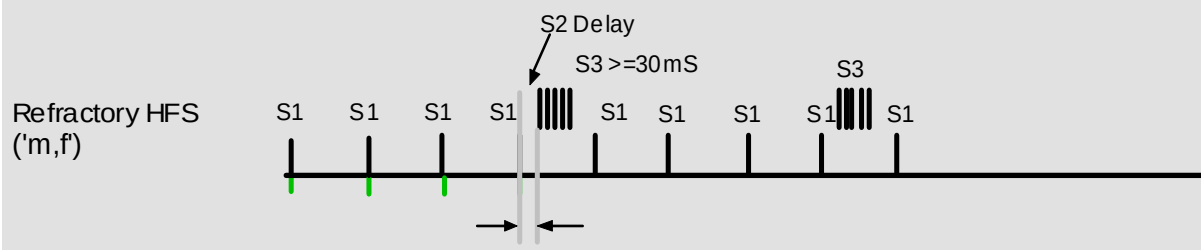
Sensed S2&S3. Multiple sensed extra-stimuli are given into different channels / chambers:

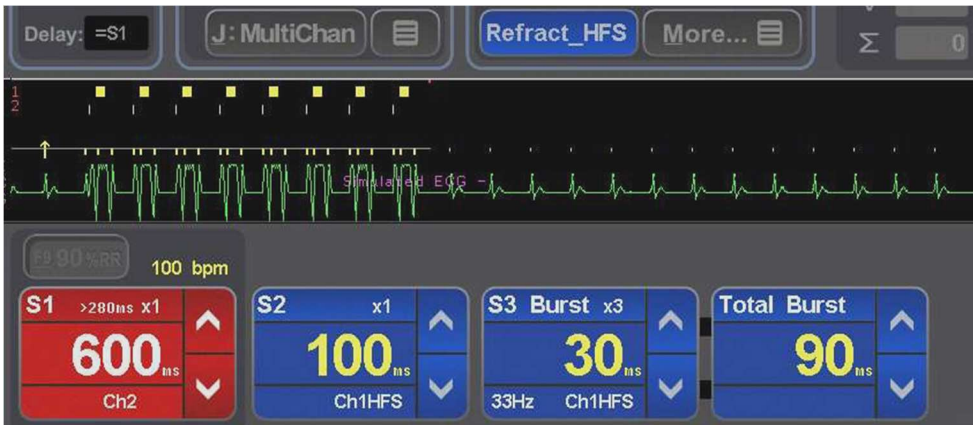


PPI Protocol. This protocol displays the Post Pacing Interval during entrainment studies of tachyarrhythmias. Protocol verifies S1 vs TCL vs PPI and if it obtains a valid set, it displays “PPI-TCL”, or if it misses the 1st sensed tahycardia complex, it displays (PPI+1)-TCL.:



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).

12.11.13 Trigger Sync output interfaces

Trigger / Sync output for your EP Recording equipment review screen is provided on the 8th sequence / train pulse in the NODAL_ERP and the MULTI_SX protocol, the first P/QRS-coupled extra-stimulus in RSYNCED_SX protocol and when pacing is stopped in SNRT, BURST_PACE, WENCKEBACH and ATP_ACID protocols. This may be adjusted in the Config menu.

12.11.14 Saving /Restoring 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.

12.11.15 Parameter persistence

Parameters in each protocol may be forced to persist during changing of protocols by setting Config Service parameter CSV36 set to ‘1’. Selecting the same protocol from within a protocol loads a fresh set of default parameter values for that protocol.

12.12 *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'. For example, the lower limit for S1 in most Protocols (other than BURST PACE and ATP_AICD) is set by Config. Var-1. To modify values, place the cursor over the variable and enter the new value. Obtain help on any variable by pressing 'H' when the cursor is over the variable.

Programming of Default Protocol Parameters. On every entry to a protocol, default protocol parameters are loaded from a Operator definable defaults Setup (Except if parameter persistance is turned on). To save new defaults for a Protocol, set up parameters in the protocol as desired and press 'Alt-S' and [Enter]. For example, if you wish to change the default S1 in the MULTI_SX protocol from the factory preset 400 ms to 600 ms, (i) set the Stimulator to the MULTI_SX Protocol (by pressing its hotkey 'z'), (ii) enter 600 into the S1 variable and then (iii) save the setup for MULTI_SX by pressing 'Alt-S' and then [Return]. Default values for other parameters such as SyncTo, Train, Decrement and so on may be programmed similarly. The new defaults are set permanently.

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. The currently loaded Parameter setup is displayed in the top left hand part of the screen; the setup memory loaded is '1' by default. This default may be altered by Config Var-39 to any value between 1 and 8.

Restoring Factory Presets. Restore Config variables to factory defaults by selecting Config Var-40. This resets all Config variables to factory presets. All Protocol Parameters will also be set to factory presets.

Copying Protocol defaults To copy one setup to another use Setup save or restore (‘Alt-S’ or ‘Alt-R’), select the source setup to copy and press key ‘C’ then select the destination setup and press ‘P’ to paste the settings.

12.13Sound 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).

The sound is produced by an on-motherboard generator and is a low amplitude (600mV) mono signal output intended for input into amplified speaker sets only. The following configuration parameters control sound output.

User Configuration	Explanation
8: Sound Output Source	❑ Sound can be generated to different output. Options are as following, 0 – No sound output 1 – PC internal speaker output only 2 – PC external speaker output only 3 – Both PC speaker output (Default)
37: Sense Sound	❑ Duration of beep made with every QRS sense. ❑ Default 0 for silent; typically 10 to 20ms for soft sounds. ❑ 5=soft, 10-20medium, 30-100 loudest (still pretty soft though). ❑ Default is 0. Range is 0 to 100ms.
38: Pace Sound Duration	❑ Duration of beep made with every stimulus ❑ Default is 20ms. Range is 0 to 100ms. ❑ Range 00-99 controls the PC Sound Speaker ❑ Range 0100-9900 controls the SGU Sound Speaker ❑ Eg. 2510 specifies 10ms for PC Speaker and 25ms for SGU speaker. ❑ Eg. 0000 specifies both speakers off.

Service Configuration:	Explanation
7: Pace (S1) Sound Pitch	❑ Pitch of sound (in Hertz) emitted on every non-extra S1 pacing stimulus (S1). ❑ Range 50 to 9000Hz. Default 1000 Hz.
8: Extras(S2-7)Sound Pitch	❑ Pitch of sound (in Hertz) emitted on every S2- S7 extra-stimulus ❑ Range 50 to 9000Hz. Default 1000 Hz.
9: Sense Sound Pitch	❑ Pitch of sound (in Hertz) emitted on every sensed ECG peak. ❑ Range 50 to 9000Hz. Default 1000 Hz.

WARNING:

In order to prevent patient micro-electrocution by excessive enclosure or auxiliary currents, any connected amplified speakers must be powered by a medically isolated mains power source, such as the Micropace Isolation Transformer MP3107; never connect to non-isolated mains.

12.14 Safety Features

Backup Manual Pacing. Failure of the computer is detected by the Stimulus Generator Unit, which displays an error message 'No PC' on its LED display; after several seconds the SGU enters BACKUP MANUAL PACING mode (or the user may force this mode by pressing the BACKUP ENABLE button), whereupon the Stimulus Generator Unit functions as a stand-alone programmable pacemaker. This mode is indicated by the absence of the PC PACE LED and lighting of two 7-segment LED numerical displays on the front panel indicating set PACING INTERVAL and CURRENT. These can be adjusted by pressing adjacent up/down arrows. Pacing may be then toggled on/off by the red PACE ON/OFF button. This mode may be forced by the Operator, e.g. if the computer appears to be malfunctioning by pressing the BACKUP ENABLE button at any time.

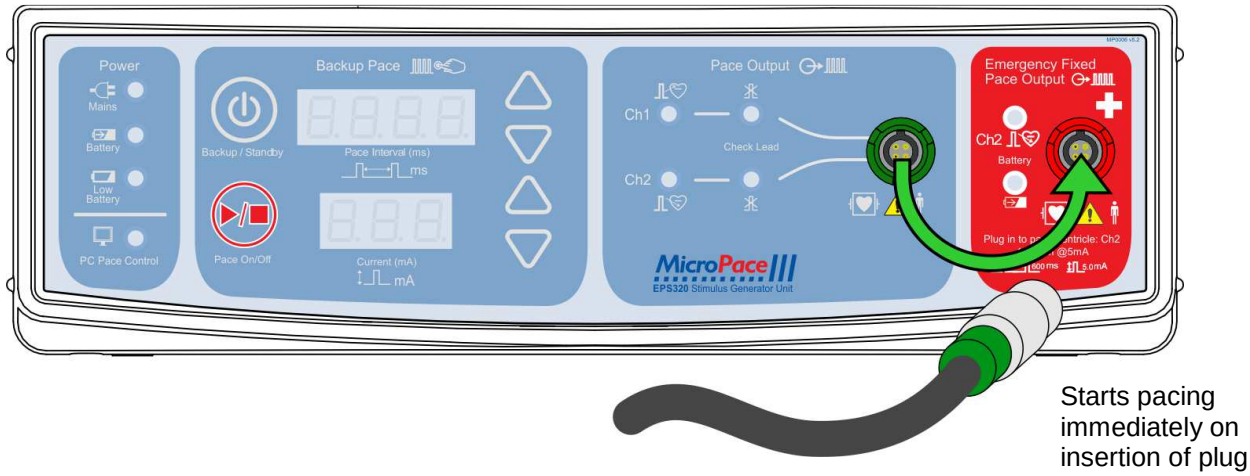


Figure 21 Connecting to Emergency Fixed Rate Pacing output.

Emergency Fixed Rate Backup Pacing. Should the Stimulus Generator Unit itself appear to fail by a lack of stimulation pulses or by displaying an alarm on its LED display and the patient requires urgent pacing, an independent analogue circuit pacemaker is available for emergency pacing. Remove the green Stimulus Cable plug from the green PACE OUTPUT socket on the Stimulus Generator Unit front panel and plug it into the red EMERGENCY FIXED RATE BACKUP PACING socket immediately to the right of it (Figure 21). Pacing will start immediately (by sensing the applied lead resistive load) at 100bpm, 5mA and 2ms pulse into the VENTRICULAR channel only. This emergency facility has a separate battery and will function even in the unlikely event of a failure of all other systems.

Other safety features in the Micropace Stimulator include:

(i) Software advisory messages to Operator of inconsistent or potentially dangerous Operator actions, such as pacing intervals less than 230 ms

(ii) Operator adjustable software safety functions and limits on protocol variables such as S1 to S7, QRS Sync timeout and Idle keyboard safety lockout, all adjustable in the Config Menu.

(iii) Backup battery in the Stimulus Generator Unit in case of loss of external power.

(iv) Extensive Stimulus Generator Unit power-on self-testing and safety self-monitoring.

(v) Defibrillation proof Stimulator outputs.

NOTE: A separate backup External Temporary Pacemaker must be readily available for use in the event of a patient becoming pacemaker-dependent.

12.15Software 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 means that the computer was too busy to produce accurate timing of stimuli, i.e. stimulus was issued a little too late. It 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.

12.16 Additional Software Message

12.16.1 Advisory Message

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.

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.
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.
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.

Software Related Advisory Messages	Explanation	Suggested Action
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.

12.16.2 Text Messages

Advisory Notes (NOTE…)	❑ These messages inform user of required instructions or informative data and are self-explanatory ❑ 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…) Run Time Error Messages (RUN_ERR…)	❑ Significant errors found, stop using the Stimulator and contact your distributor or Micropace for service.

12.17 Configuring the Program - the CONFIG menu[2]

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.

A number of parameters controlling the program's operation are stored in a configuration file and may be altered by the Operator.

The configuration menu is called up by hotkey 'K'. The variables are displayed in a numbered sequence. To change one, chose it's number and then enter the new value. You may also use arrow key to place cursor on the variable and enter the new value. Press 'h' to obtain help on variable under the cursor; this will tell you its meaning, value ranges, default values and any related variables. The parameters are shown in Table 8.

User Configuration password is: **"henry" or 4546.**

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

```
+------- EPS320 Ver:4.0     USER - Configuration      Protocol: Pace  -------+
|                                                                            |
|  >>PGDN/Enter->Service Page  ---    --³  21 Min.auto Sx for RSync_Sx :      ms|
|  1 Minimum S1 for PACE      :       ms³  22 Tachy Detect Interval    :      ms|
|  2 Absolute Min S1,eg BURST:       ms³  23 His-coincident RSynced_Sx:      ms|
|  3 Minimum  Sx (S2-S7)      :       ms³  24                          :       |
|  4 Min.auto S1 for ATP      :       ms³  25 Temp Prot.Boosted Current:      - |
|  5 Min.auto S1 WENCKE/SNRT  :       ms³  26 ECG gain Atrial Chan     :      - |
|  6 Min.auto S1 for BURST    :       ms³  27 ECG gain Ventric Chan    :      - |
|  7 Burst -> Overdrive Burst:        - ³  28 ECG gain Ext1            :      - |
|  8 Sound Output Source      :       - ³  29 ECG gain Ext2            :      - |
|  9 F9 %RR Percentage        :       - ³  30 Soft QRS Detect Setup    :      - |
| 10 Sync1out on(Train+1-n)S1:        - ³  31 QRS Blanking Time-HWare  :      ms|
| 11 Decr/Incr N'ERP by Table:        - ³  32 QRS Sync Timeout         :      ms|
| 12 W'ke/Brst Autodec'Period:       ms³  33                          :       |
| 13 SNRT Auto Stop           :         ³  34 No of Hints (15,0=off)   :      - |
| 14 SNRT Duration            :       s ³  35                          :       |
| 15 Repeats Multi_Sx Extra's:        - ³  36 Idle Safety Timeout      :       s|
| 16 En Wencke Log Decremt'n :        - ³  37 Sense Sound              :      ms|
| 17 En Wencke Beat Decrement:        - ³  38 Pace  Sound Duration     :      ms|
| 18 Rate-adaptive Burst S1   :       % ³  39 Default Setup   No.(1-8) :      - |
| 19 ATP Intraburst Decrement:        - ³  40 Set Global FACTORY PRESET:      - |
| 20 Touch Scrolling of Menu :          ³  41 Initial Input Method     :      - |
+----------------------------------------------------------------------------+
```

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_AICD 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 (15,0=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.
37. 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

12.18 Summary of Hot Keys.

A	Atrium Ch1	Set stimulation to output to Atrium-Ch1 channel
B (P)	Burst	Burst protocol - rapid pacing for set number of pulses.
C	Current	Set stimulus Current amplitude.
D	Decrement	Decrement automatically S1 in Wenckebach protocol, Current in Threshold, etc.
E	delayEd	AV delayed (sequential) pacing, S1= rate, S2= AV delay.
F	FlipPage	Flip between Stimulator A and B, same as PgUp and PgDown
H	Help	Show context specific help menu.
I	TraIn	Set number of pulses in stimulation train in Burst pace, ATP_AICD, etc.
J	SxTable 1-4	Simultaneous Atrial and Ventric pacing, selectable for drive train and extra-stimuli.
K	Configure	Configure Stimulator's global defaults and safety limits.
L (tP)	ATP_AICD	AICD style Anti-Tachycardia Pacing facility, with S1 calculated from % RR interval.
M	Procedures	Display menu of EPS Procedures.
N (P)	Nodal_ERP	AV node refractory curve protocol, Atrial pacing for anterograde, Ventric. for retrograde.
O (tP)	Overdrive	Temporarily jump to Overdrive pace protocol, remembers S1 from last jump.
P (P)	Pace	Constant rate pacing Protocol.
Q	Quit	Quit Stimulator program.
R (P)	Rsynced_SX	R-synchronized or sensed extra-stimuli.
S (P)	Snrt	Sinus Node Recovery Time Protocol; use INS to set successive S1 values.
T (P)	Threshold	Perform stimulus capture threshold protocol; sets double threshold current automatically.
U	Duration	Set duration of stimulus pulse.
V	Ventric Ch2	Set stimulation output to Ventricle-Ch2 channel
W (P)	Wenckebach	Set decremental pacing (Wenckebach) protocol.
y	Sync1stS1	Toggle QRS synchronization on/off.
Z (P)	MULTI_SX	VT induction protocol, Programmed ventricular stimulation.
1-9		Digit entry for S1-S7 and other parameters.
F1-F7/**S1-S7**		Focus/enable S1-S7. Quick double strike of S2-5 increments by 10 ms; F6/F7 plays macro.
F8 / **Pause**		Focuses PAUSE parameter in relevant protocols.
F9 / **%RR**		In protocols with S1 only, sets S1 to 90% of RR.
F11	Over-drive	Push-button Overdrive pace, returns on stopping pacing.
F12 / **+** (Red on White cross).		EMERGENCY PACE - pace at 600ms, both channels, 2 x Current ampl., immediately.
←/ → (arrows)	Move focus	Move focused (red) zone left/right.
↑ / ↓ (arrows)	Move focus	Move focused (red) zone up/down.
+ / - (keypad)	Change value.	Increment / Decrement value of focused parameter.
DEL	Turn Off	Turns off focused parameter–Decr-auto/Sync-to/S2-S7; Pause->repeat, Train->Infinite.
INS	Insert/Edit	Restores focused parameter from DEL; Edits parameter where allowed.
‘	Ch3	Set stimulation output to Ch3 with Stimulus Multiplexer Box, else Ch1
/	Ch4	Set stimulation output to Ch4 with Stimulus Multiplexer Box, else Ch2
`	Safe	Place keyboard into Safety Lockout, until Esc Key is pressed
END	Auto Lock	Master on/off toggle for all automatic decrementation.
Spacebar/**PACE**		Brief press toggles pacing On / Off; prolonged (>300ms) press paces only while pressed.
PGUP/PGDN	Stim Page	Flips between Stim Page A and B.
Alt-d	Sx Decrement	Decrements focused Sx instead of the default highest enabled Sx.
Alt-e	Extras Log	Displays the 20 most recently used stimulation protocol parameters.
Alt-s	Save	Save protocol parameters as displayed & make parameters default for all future sessions.
Alt-r	Retrieve	Retrieve one of eight saved protocol setups or factory presets.
Alt-l	Lock	Master on/off toggle for all automatic decrementation.
Alt-f	Off	No sensing site - no sensing will occur.
Alt-h	Sense Help	Help on sense site.
Alt-a	Atrium-S	Sense QRS from Atrial channel catheter tip.
Alt-v	Ventr-S	Sense QRS from Ventricular channel catheter tip.
Alt-1	Ext-1-S	Sense QRS from External ECG1 channel.
Alt-2	Ext-2-S	Sense QRS from External ECG2 channel.
Alt-x	Auto_ext	Automating sense site - pacing Atrium uses Ext ECG-1, pacing Ventr uses Ext ECG-2.
Alt-i	Auto_tip	Automatic sensing from the paced catheter tip (pacing electrodes)
Alt-u	Up-Decr	Negates (makes negative) AUTO_DECREMENT parameter to cause incrementation.
Alt-m	Hotkey Menu	Displays multi-page menu of hotkeys, starting with this page.
Alt-t	Timer	Strikes of this hotkey successively activate, stop and delete a simple Timer display.
Alt-q	QRS Detect	Opens Software QRS Detect menu – for adjusting QRS Detection.
Ctrl-DEL:	Mask Sx	Masks focused Sx (for Current parameter, reverts from Ctrl-INS).
Ctrl-INS:	Unmask Sx	Unmasks focused Sx, (for Current, increases current to 20mA-Para-hissian pacing).
ESC	Escape	Exits from menus and returns focus to Protocol-specific screen Home position.
BSP	Undo	Step back in decrementation to previous value – in SNRT, Nodal_ERP, Multi_Sx.

Table 9 Summary of Hotkeys

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, which switched under computer control into the four outputs of the SM-Box according to the PACE_SITE setting in the Software.

The SGU must be connected to the serial COM1 port on the computer using only the supplied custom made RS232 connection cable, MP3033A.

13.1 EPS320 Stimulus Generator Unit layout

The front panel, shown in Figure 22 has four sections described below from left to right:

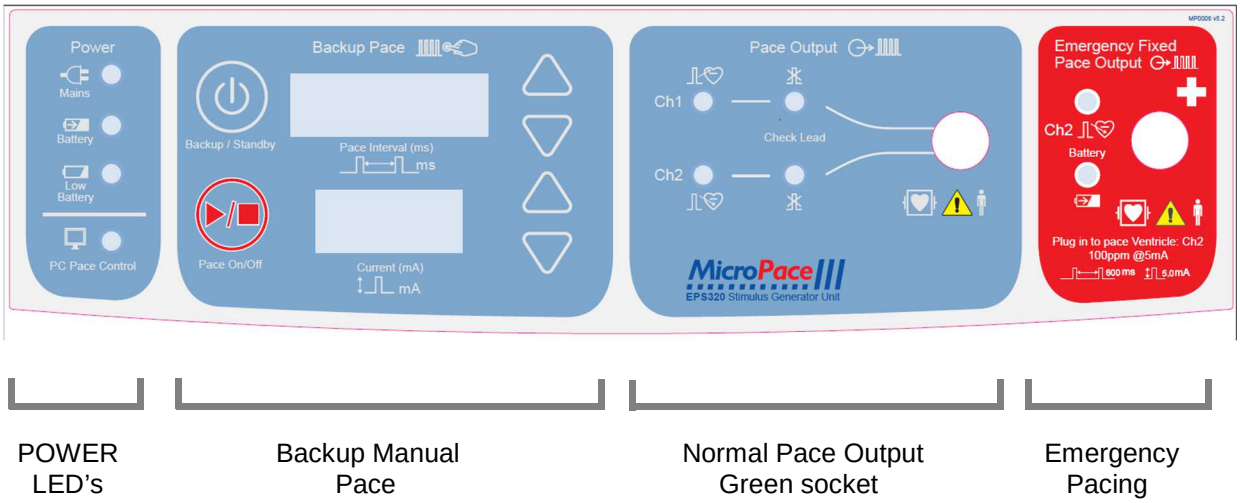


Figure 22 EPS320 Stimulus Generator Unit front panel (reference only)

Four power indicator lights on the extreme left:

(i) Main 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.

Backup Manual Pace Control:

This section located in the left middle of the front panel is a backup system and is normally inactive. Should the computer fail due to power failure, hardware failure or software crash, the Stimulator will detect the loss of communication from the Computer (due to loss of watchdog transmissions) and automatically switches into the Backup Manual Pace mode. This mode may also be manually selected by pressing the BACKUP / STANDBY button. The red 7-segment LED numerical display will light up showing default values for Pace Interval (600ms) and Current (5mA). These may be adjusted by the up/down arrows on the right of the display. Pacing may then be toggled on/off by pressing PACE ON/OFF button. Note that pulse width is fixed at 2ms.

Pressing the BACKUP / STANDBY button when the Stimulus Generator Unit is already in Backup Manual Pace Mode sends the Stimulator to Sleep Mode i.e. low power consumption standby mode. This is the mode that the Stimulator adopts on exiting the Stimulator computer program. The Stimulus Generator Unit may be awakened by turning the computer on and running Stimulator software or by pressing the BACKUP / STANDBY button once more.

Pace Output:

Two green LED's marked Atrium and Ventricle light briefly when stimulation pulse is generated (NB the LED blink duration is made longer than the pacing pulse duration for visibility.

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.

The following graphs indicate the maximum deliverable current into given pacing lead impedances and the maximum impedance for a given programmed current, above which High Impedance message will be issued.

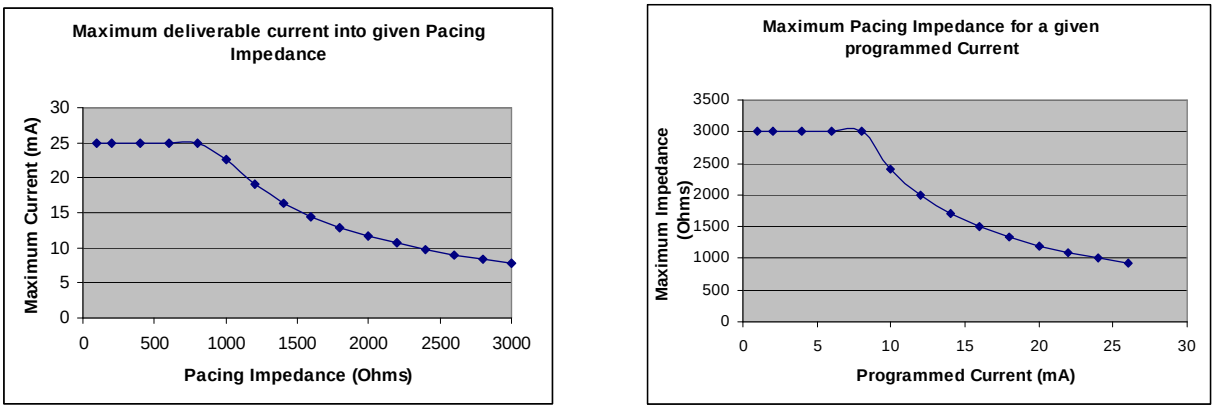


Figure 23 Stimulator output characteristics

Emergency Fixed Pace Output:

This is a last resort backup system. 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. A loud buzzer will sound between each pacing pulse indicating emergency mode of operation of Stimulator.

The BATTERY green LED will light after a brief delay of about 2-3 seconds indicating that battery has adequate charge. If it fails to light, then pacing may no longer be reliable and the battery should be replaced at the earliest opportunity. The PACE V green LED will normally blink with each stimulus. If it fails to do so and/or no sound is emitted by the circuit, then pacing is probably not occurring and the patient should be connected to an alternative external temporary pacemaker as soon as possible.

This emergency circuit is completely independent from the remainder of the Stimulator. It is powered by its own 9V Lithium battery with a shelf life of 10 years in standby mode and has independent defibrillation protection.

Information Displayed During Normal Operation:

The two LED 7-segment numerical displays in the Backup Manual Pace section are also used to display information during normal power on self test (POST) and when errors occur (see below).

When the Stimulus Generator Unit is switched on, the unit will normally display the following, in the PACE INTERVAL and CURRENT displays, shown here side by side:

StAn dby	indicating transition to the Standby Mode and then
	Nothing, which together with the lit green MAINS POWER LED, indicates the Standby Mode.

Upon turning on of the computer and the PC connecting to the Stimulus Generator Unit, the display shows the following:

PC tESt	indicating the PC Pace Controlled mode, indicated also by the lit green PC PACE CONTROL.

Upon pressing the BACKUP ENABLE button to activate the Backup Manual Pace mode, the display shows the following sequence of data:

SELF tESt	indicating the self test is in progress,
EPS 320	indicating the model of the device,
VEr 4.76	indicating the firmware version,
BAtt 15.5	indicating loaded battery voltage, and finally,
600 5.0	indicating the default pacing interval and pacing current in the Backup Manual Pace Mode.

13.2 EPS320 Stimulator Connections

Figure 24 shows the connectors on the rear panel of the Stimulus Generator Unit.

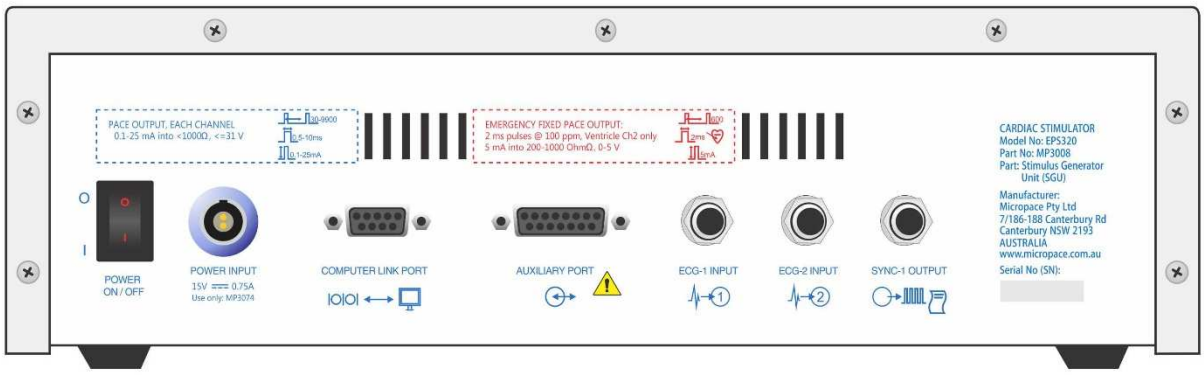


Figure 24 Connectors on rear panel of SGU (reference only)

Power On/Off

This is the main power switch to the Stimulus Generator Unit. In the Off position the units is without power, however, the MAINS POWER indicator glows yellow if external power remains connected to the Power Input socket. In the On position, the unit draws power from the external power supply or if during operation external power fails, then from the internal backup lead acid battery. The SGU is not intended to be powered up from Off state without external power and backup battery alone (except when 100% charged) will generally not power up the SGU from Off state.

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. The internal lead-acid battery requires a float charge of 14.1 Volts for full charge. Input voltage is reverse polarity protected.

Computer Link Port

Serial RS232 data link to computer's COM1 Port; DB9 connector. Use only Micropace Serial RS232 Boost Cable (Part No. MP3033A), as this has EMC and ESD protection built into the computer end D-connector required for compliance with the relevant European Community Directives. Other cables may cause the Unit to radiate unacceptable levels of electromagnetic radiation and/or be susceptible to electrostatic discharge.

The Micropace Serial Boost RS232 cable is a straight-through connected cable; (null modem cable will not function). Only four pins are required to be connected: 2(Tx),3(Rx), 4(Gnd) and 5(DTR-µP Reset).

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 KΩ. Gain may be configured with the CONFIG VAR 28 'ECG gain Ext1' variable for input voltage ranges of ±0.5V or ±1.0V. ECG sensing may be selected from either of these external ECG Inputs (or from the pacing electrodes of either pacing channel) via the SENSE_SITE menu. This ECG source will become the source for the software QRS detector and will be displayed on the screen. The ECG is sampled with 8-bit accuracy at 500 samples per second.

Sync-1 Output

This port delivers a CMOS logic (positive 5V) logic 200 ms logical pulse at various times during stimulation. It is provided to allow use of the common 6.5mm Phone plug connection system.

Auxiliary Port

This port allows connection to above ECG Inputs and Sync output as well as two further Sync outputs and two Sync inputs via a single DB15 connector. It may also be used to control the Stimulus Multiplexer Box. Refer to the Service Manual for details.

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.

Most of these errors are preceded by a 'countdown to error' phase, signalled by a countdown from 7 to 0 in the lower window, when pressing the 'Pace On/Off' button attempts to reset the error. If you suspect a false alarm due to interference, for example, you have applied RF ablation very close to the stimulation electrode, press the Pace On/Off button to attempt to reset the error and continue to use the Stimulator.

Most of these errors, except the communications-related ones, cause a help screen to appear on the computer screen. Refer to Table 10 below.

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 while unit on Battery power. Stimulus Generator Unit cannot function.	Reconnect external power and press Backup Enable button.
b,A,t,t,,L,O	Battery Low	Backup Battery < 8.6V during self test. The Stimulator will not function on backup battery, 1.e. it will not function without external power.	You may continue to use the Stimulator if you have external power connected. 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 have Emergency Pace Battery replaced.
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 ablation voltage). This may cause unwanted arrhythmias.	Disconnect Stimulator from the patient. Remove any interference from the Stimulator outputs. Reset 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 10 Tabulated Error messages

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 power down and power up 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 are 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.

Regular pacing produces irregular stimulus symbols on the screen.

(i) If Stimulation appears regular:

- This may occur if you were altering a parameter repeatedly during rapid pacing, or continuously pressing a key and is due to the computer having insufficient time to attend to all these low priority tasks, which includes sound-generation. Actual Stimulus timing, however, will be accurate because the software gives it the highest priority.

(ii) If Stimulation pulses are irregular:

- The program will issue an error message "Stim Overrun" to warn you should this occur (see the Error Messages section above).

The Generator does not pace, 'dC Err' appears on Stimulus Generator Unit.

(i) Cause of problem:

- A 'dC Err' appears on the BACKUP MANUAL PACE LED display and a pulsed high-pitched sound is emitted. This signifies a hardware or firmware failure in the Stimulus Generator Unit causing possible continuous stimulation of the myocardium - i.e. DC current on the output. This could potentially induce ventricular fibrillation - disconnect the patient by unplugging the green patient lead from the Pacing Output connector on the front of the Stimulus Generator Unit.

(ii) Emergency pacing:

- If emergency backup pacing is required, you can use the EMERGENCY FIXED PACE facility by plugging the patient lead into this red socket (see above).

No Triggering of attached EP recording system's display screen.

(i) Check integrity of the electrical connection between the SYNC-1 OUTPUT 6.5mm phone jack connector on the back of the Stimulus Generator Unit and the EP recording apparatus.

(ii) Ensure also that the CONFIG VARIABLE 'Sync1_out (Train+1-n) S1' is set to a value less than or equal the TRAIN parameter (e.g. 1) so that a sync pulse may be issued during the train sequence, else no pulse is issued.

(iii) Check that the EP recording apparatus is correctly configured to sense incoming trigger pulses.

Troubleshooting The Touch Screen (for optional LCD Touch screen only).

(i) The Stimulator software detects and verifies presence of Touch Screen, drivers and correct configuration Service Var 31; appropriate messages are generated and touch software disabled if any deficiencies exist.

(ii) If touch screen is blank:

- Verify that display is switched on at the power switch on the side of the screen and Bona PC is switched on.
- Verify that video cable is attached between the touch screen and Bona PC.
- Substitute another LCD computer screen – if image appears then the touch screen is at fault, otherwise the Bona PC may be at fault.

(iii) Touch screen displays picture but is not responsive:

- If PACE ON/OFF button displays “Touch Disabled” then verify that touch screen is enabled at the “Input” button; “Touch” or “Both” should be present.
- Verify serial COM cable from touch display to Micropace is connected into COM2 of Bona PC.
- Verify that Configuration Service Var 31 En Touch Screen Software is set to 1.
- Quit and re-launch software and note any error messages displayed – such as absence of Touch drivers; if error messages then re-install software from backup directory by selecting corresponding item on displayed menu.

(iv) If LCD Touch screen does not respond appropriately to touch whereby it activates unexpected menus or parameters,

- The LCD Touch screen probably requires recalibration. In the stimulator software, go to the ‘Help Menu’, select ‘Touch Calibration’ to perform calibration of the LCD Touch screen. Follow its instructions carefully. If situation is not resolved, the touch screen may need repair.

15 USING THE OPTIONAL FOUR CHANNEL STIMULUS MULTIPLEXER BOX

The Stimulator software re-programs and switches the two physical Stimulus Generators between the four outputs to create a virtual Four-channel Cardiac Stimulator. This allows a number of special multi-site pacing protocols described in Specialized Protocols section above.

15.1 Stimulus Multiplexer box (SM-Box) features

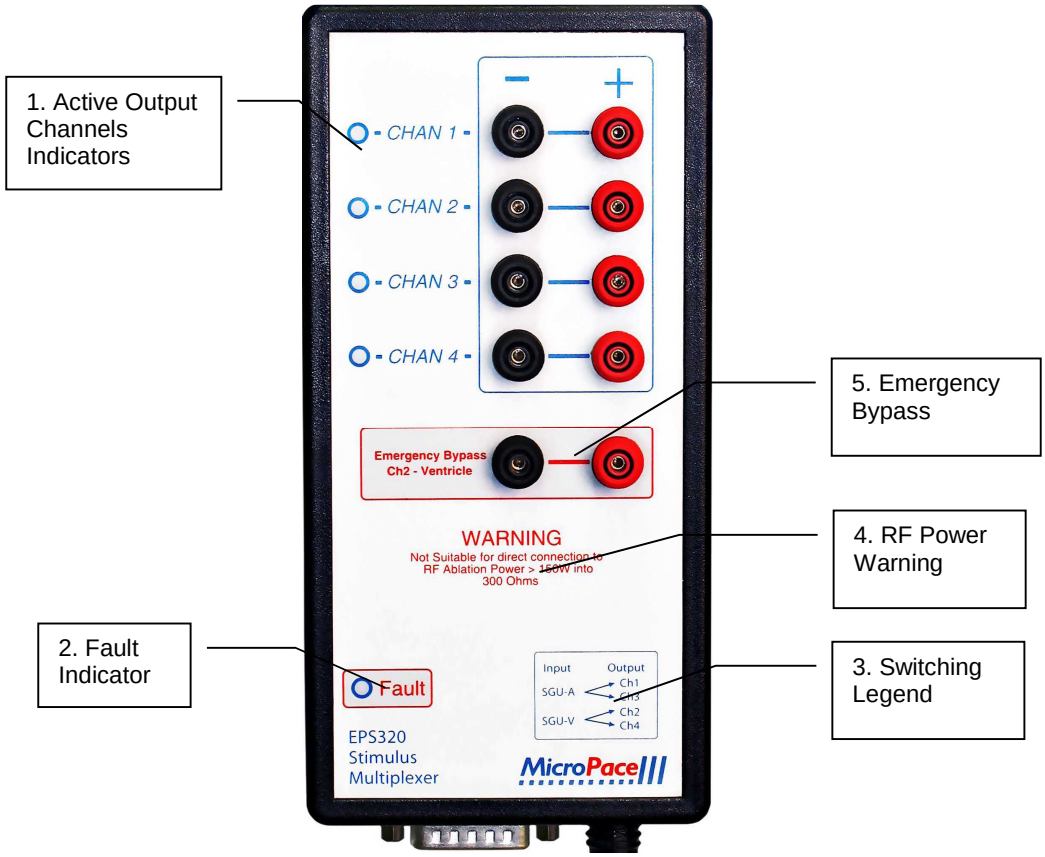


Figure 25 Details of the SM-Box labelling

1. Active Output Channels Indicators

Two green indicators light next to the active output channels. In the Bi_Ventric (Three Channel Pacing) protocol, Chan 2 and Chan 3 indicators flicker and relays click with each stimulus set; this is normal operation. In all other circumstances, if fewer or more than two green indicators light at a time, then SM-Box is faulty. Note that when Control Cable is disconnected from the SM-Box, no indicators light, and Input Stimulus channels are switched to Outputs 1 and 2 by default.

2. Fault Indicator

Fault Indicator lights red to indicate failure of switching function of Stimulus Multiplexer; use Emergency Bypass outputs. Note other indicators of failure in Section on Troubleshooting above. In case of SM-Box failure or disconnection, the Stimulator Software Ver 3.19 or above, will display a message to that effect, if software is configured for the SM-Box.

3. Switching Legend

This indicates the switching function of the SM-Box. The Stimulus Generator Atrium output is switched to either output Ch1 or Ch3 and Ventricle into Ch2 or Ch4.

4. RF Power Warning

Use of excessive RF power will heat up the protective components in the SM-Box, possibly leading to failure of the SM-Box, a potential fire hazard and a reduction in RF power applied to the patient.

5. Emergency Bypass

This is an emergency direct connection to Ch2-Ventricle on the SGU / software interface. In case of failure of SM-Box, remove stimulus connectors leading to electrodes in the patient's ventricle from the normal SM-Box outputs and insert them into these two sockets. You may then start pacing either into Ch2-Ventricle or use Emergency Pace hotkey on the stimulator software. In case of software failure, you may also pace using Backup Enable / PACE On/Off on the Stimulus Generator Unit (SGU) or the Emergency Fixed Rate Pacing red output socket also on the SGU. If patient is pacemaker dependent, then use an approved temporary external pacemaker generator connected directly to intra-cardial leads as soon as possible.

15.2 Software Support

In the Micropace Stimulator Software, select any one of Channels 1 to 4 from the Pace Site menu to pace into that channel. The output stimulus pulse with the displayed current amplitude and duration appears on the corresponding output channel. Select Joined 1+2 or 3+4 to pace simultaneously into two channels.

Select Three_Channel_Pacing from the Procedure menu (hotkey ‘m’) to pace consecutively into three chambers; for example this may have application for biventricular pacing.

Figure 26 Pace Site Software Menu

16 MAINTENANCE

16.1 Batteries

(i) The Backup 12V lead-acid gel battery trickle charges from the external 15VDC Power Supply during pacing. You should therefore always run the Stimulator with the External Power Supply connected. Expected life span of the type of battery supplied is about 4 years and it should be replaced every 3 years. If the Stimulator is used on battery power, ensure that the battery is recharged before the next clinical use (a fully depleted battery takes approximately 20 hours to recharge; charging continues during use of Stimulator).

(ii) Ensure that EMERGENCY FIXED PACING OUTPUT functioning is checked once every 6 months, either at routine maintenance or by using it briefly during an EPS study to ensure that patient capture is effected. The computer checks the emergency battery on every power up and warns the Operator if low. This battery must be replaced after 7 years from the date of manufacture, as the expected life span of the type supplied is 10 years.

(iii) Note that once BAT OK fails to light during emergency pacing, the circuit may be unable to deliver full maximal output voltage, but will continue to deliver usual current into normal impedance for many hours. The Emergency battery may be replaced at a convenient time, perhaps at the end of the session.

(iv) Replace the Emergency Fixed Rate pacing 9V battery 7 years after date of manufacture with an Ultralife U9VL, 9V lithium manganese PP3 style battery from Micropace or Farnell PN 299390.

(v) Replace the Backup 12V battery 3 years after date of manufacture with a Yuasa/Genesis NP2.3-12-FR, 12V 2.3 Ah sealed lead-acid battery, from Micropace or Farnell PN 174786.

(vi) A Battery Replacement Information label may be found on the underside of the SGU on units shipped from March 2006 onwards

16.2 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) Annual preventative servicing should include:

- Calibration. Stimulus Current and Duration accuracy should be checked every 12 months. This is performed by placing a 1kΩ (1%) resistor across the channel output posts and measuring with an oscilloscope the Current amplitude and duration for set values throughout their range. Calibration is factory preset by use of 0.1% voltage reference, 0.1% resistors and an A to D converter. There is only one adjustable component per channel in the Stimulus Generator Unit - zero current offset; this affects accuracy of current only in the range of 0.1 to 0.5mA. If incorrect parameters are found then the Stimulus Generator Unit requires servicing by qualified personnel.
- Perform electrical safety tests to IEC60601-1 /UL2601-1 using a suitable commercial tester, in particular verify (i) summation of the earth leakage current does not exceed 50 µA, (ii) patient isolation and patient and mains on applied part leakage currents, measured preferably at bedside patient output box to include entire installation, or at Stimulator outputs.
- Checking batteries for signs of damage or loss of function and replacement of inadequate batteries or those due for replacement.
- Checking LED's function on POST.
- Ensuring that all external cables are not damaged and are securely fastened into their receptacles.

- Cleaning the computer's cooling grille, cleaning externally by vacuum cleaning is acceptable.
- Running the ROMDOS chkdsk.exe utility software on hard disk C: to diagnose any bad sectors; do not attempt to fix any errors – contact the distributor if errors found.

16.3 Cleaning Instructions

(i) The Stimulator system should be kept clean to ensure reliable operation.

(ii) 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 into the keyboard, the Stimulus Generator Unit or the computer. Any spillage should be cleaned immediately and the unit sent for service as soon as possible to minimize damage to components.

(iii) 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.

(iv) Touch Screen

- The Touch Screen is not suitable for sterilization. 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. Put the cleaner on the rag and wipe the touch screen. Never apply the cleaner directly on the touch screen.
- Do not use alcohol (methyl, ethyl or isopropyl) or any strong dissolvent. Do not use thinner or benzene, abrasive cleaners or compressed air.
- To clean the display unit cabinet, use a cloth lightly dampened with mild detergent.
- Avoid getting liquids inside your touch monitor. If liquid does get inside, have a qualified service technician check it before you power it on again.

16.4 Serviceable Life and Disposal

(i) The Stimulator system and its accessories have an expected life span of 7 years and will be supported by Micropace for this period.

(ii) Upon decommissioning, the lead acid battery should be removed from the Stimulus Generator Unit and disposed of in an approved disposal or recycling facility for lead and acid-containing products. The Emergency 9V battery contains no lead and may be disposed of with the rest of the unit in compliance with the applicable local waste control regulations. If you have any questions about disposal, contact Micropace or its distributor. Recycling Passport document is available on the Micropace website 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.*

17 EPS320 AND STIMCOR™ SPECIFICATIONS

i. System

Stimulus Controller:	Embedded micro-controller in SGU
User Interface:	PC windows-style graphical display
Weight	25 kg gross
Power:	110-240VAC 50-60Hz, 90VA max. (40VA standby) , Class II
Isolation transformer:	110-240 VAC, 300 VA, IEC60601-1

ii. Computer

CPU:	VIA-Eden ESP™ 533 MHz or similar
Weight:	5.65 kg, with monitor and keyboard
Dimension:	CPU: 23.4x4.8x17.5 cm, 15" Monitor, 101 Keyboard
Hard Disk:	64Mb Compact Flash Card
Power Source:	100-240 VAC to 12V DC 5.0A PSU (via isolation transformer)
O/S Software:	Custom RTOS / Datalight ROM-DOS

iii. Stimulus Generator Unit

Main power source:	100-240 VAC to 15 VDC 1.2 A PSU
Backup power:	12V 2.1 Ah sealed lead acid
Emergency power:	9V $LiMnO_2$i PP3, 10y life
Weight:	5.3 kg including batteries & PSU
Dimensions:	31.5cm x 34.0 cm x 9.5cm
Power Consumption:	800 mA peak during operation 40 mA in standby mode
Operating Time:	Indefinite with mains connected Two (2) hours on backup battery

iv. Pacing Channels

Isolated Channels (3):	(i) Atrial and (ii) Ventricular via green Redel 4 pin socket (iii) Emergency Fixed Pace Output to Ventricle, via red Redel 4 pin socket
Power Source:	Internal DC-DC converters
Circuit Isolation:	Compliant with IEC601-1, Class CF, 5kV, common & differential mode

v. Computer Controlled Stimulus Pulses

Current:	0.1 to 25 mA
Current Steps:	0.1 mA
Accuracy:	± 2% or ± 0.2 mA, which ever is greater
Pulse Duration:	0.5 ms, 1-10 ms in steps of 1ms
Accuracy:	± 0.15 ms
Load Impedance:	200-1000Ω, <700 Ω for max current
Max Output Voltage:	27V

vi. Inter-stimulus Intervals

S1 Range:	180 - 9990 ms (Pace) 30 - 9990 ms (Burst Pace)
Stability:	Quartz computer clock, ± 30 parts per million @ 25° C
Extra-Stimuli:	6 max, S2-S7, independent
Coupling interval:	30 - 9990 ms
Accuracy	± 1 ms or 0.1% whichever is greater

vii. Pre-programmed Protocols

- ♦ Stimulation Threshold
- ♦ Anterograde/Retrograde
- ♦ SN Recovery Times
- ♦ SN Conduction Times
- ♦ His-coincident extras
- ♦ Overdrive Pacing
- ♦ AICD-type ATP
- ♦ Biventricular Pacing
- ♦ Wenckebach Periods
- ♦ Programmed V Stimulation
- ♦ Burst Pacing (to 30ms)
- ♦ Auto-decremental Pacing
- ♦ AV sequential Pacing
- ♦ Combined AV drive-train
- ♦ AF/VF induction

viii. Protocol Automation

- ♦ Auto decrement / increment: S1, S2-S7, stim current
- ♦ SNRT S1 intervals and RT calculation
- ♦ Auto pace and sense - site selection in protocols
- ♦ His-coincident extra-stimulus timing calculation
- ♦ ATP S1 calculation from % of TCL
- ♦ Trigger output on sensed ectopic beats
- ♦ Stop On Tachycardia
- ♦ All automation subject to instant operator adjustment

ix. Backup Manually Controlled Stimulation

Power Source:	12V 2.1Ah sealed lead acid battery
Pulse Current:	0.1 to 25mA
Accuracy:	± 2%, or ± 0.2mA, which ever is greater
Pulse Duration:	2ms, fixed
Pulse Interval:	100 - 1400ms, accuracy: ±1%

x. ECG Sense/Trigger

High level external -	
Two inputs:	(i) Ext_ECG1, (ii) Ext_ECG2,
Connector:	6.5mm Phone socket
Input Ranges:	1V and 2V pp for FSD
Maximum Input:	2V AC pk - pk
Frequency Range:	1 to 250 Hz, typical
Pacing catheter tip -	
Two channels:	(i) Atrial, (ii) Ventricular
Input ranges:	2mV to 36mV, 4 gains
Frequency Range:	10 to 250 Hz, typical
Either Source -	
Threshold:	Adaptive software peak detect
Lockout Period:	50 - 1000ms in software
Pace Sync Delay:	50 - 5000ms in software
Sampling- display:	500Hz, 8 bit

xi. Auxiliary Sync Inputs/Outputs

Sync1 Output:	6.5 mm Phone socket
Timing:	On any drive train pulse, on halt of pacing, on extra in R-synced S2
Pulse:	+5V CMOS level, 50 ms duration
Sync2 & 3 Output:	Used for internal functions
Sync1 & 2 Input:	Used for internal functions

xii. Emergency Backup Pacing

Power Source:	9V Lithium Manganese PP3 battery, 10 years life
Pacing Pulse:	5mA ±1.0 mA, 2ms ±0.5ms, 100 ± 20 ppm
Pace output:	Separate red Redel 4 pin socket
Control:	Pacing activated by connection of a load <1MΩ, i.e. insertion of plug connected to patient

xiii. Environmental

Operating T° Range	+5ºC to +35ºC (30% to 80% RH)
Storage T° Range	-10ºC to +60ºC (10% to 85% RH)
Storage altitude:	0 to 14,000 ft (4267m)

xiv. Certification

MDD Device Class:	Class IIb
IEC60601-1	certified
Health Canada	Class III
EMC compliance	certified
CE Marking	certified
US Regulations	510(k) Accepted

Notes: 1. Specifications may change without notice
2. Computer specifications will vary according to availability

EPS320 Device Specifications Ver 3.0, 04.04.2008
EPS320B-EU/US, PCB Ver P3.15, Sch Ver 3.08

18 STIMLAB™ SPECIFICATIONS

i. Stimulator System

Stimulus Controller:	Embedded micro-controller
User Interface:	Computer Touch Graphical Interface
Power:	110-240VAC 50-60Hz, 95VA max. (40VA standby), Class II
Isolation transformer:	110-240 VAC, 300 VA, IEC60601-1

ii. StimLab Cabinet

PC:	Bona Lex Light System SBC, CPU VIA-Eden ESP™ 533 MHz or similar
Hard Disk:	>=64Mb Compact Flash Card
Power Source:	100-240 VAC to 12V DC 5.0A PSU
O/S Software:	Custom RTOS / Datalight ROM-DOS
Remote Trunk Cable:	Length: 17m (55.7 feet), 10mm o.d. Connector: Single Cannon Trident series bayonet 23 pin cable reverse connector, max diam. 34.3mm
Local Screen Cable:	1.25 meters (4 feet), integrated cable
Weight:	7.3kg (11.0kg with all external cables)
Dimension:	400 x 300 x 122 mm (cabinet)
Video Extension:	Gefen Extendit VGA Extender SR

iii. Remote Touch Screen

Monitor type:	ELO Entuitive ET1529L, 15” LCD
Touch technology:	AccuTouch Five-Wire Resistive
Power rating:	Input: DC 12V / 2A (max.)
Mounting:	Integral stand or VESA 75mm mount
Cable Length:	4 meters (13 Feet)
Dimension:	354 x 301 x 285mm
Power Consumption:	On: 50W max., Sleep: 4W, Off 2W
Sealing:	Resistant to splashes, IPX0
Standard stand tilt:	0° to 45° from vertical
Weight:	16.2 lbs (7.4kg)

iv. Optional Remote Touch Screen Roll Stand

Height:	31” (79 cm) to 45.5” (115.5 cm)
Lift Mechanism:	Gas spring assisted
Counterweight:	Built-in 10 lbs (4.5 kg)
Screen tilt range:	-20° to +30° from vertical
Weight:	38lb (17.3kg)
Mount:	VESA 75mm Display mount

v. Stimulus Generator Unit

Main power source:	100-240 VAC to 15 VDC 3.1 A PSU
Backup power:	12V 2.1 Ah sealed lead acid
Emergency power:	9V $LiMnO_2$i PP3, 10y life
Weight:	5.3 kg including batteries & PSU
Dimensions:	31.5cm x 34.0 cm x 9.5cm
Power Consumption:	800 mA (12W) peak during operation 40 mA (0.6W) in standby mode
Operating Time:	Indefinite with mains connected Two (2) hours on backup battery

vi. Pacing Channels

Isolated Channels (3):	(i) and (ii) via 4 pin Redel socket (iii) Emergency Fixed Pace Output to Ventricle, via red Redel 4 pin socket
Power Source:	Internal DC-DC converters
Circuit Isolation:	Opto-coupled, 5kV CM and DM

vii. Computer Controlled Stimulus Pulses

Current	0.1 to 25 mA
Current Steps:	0.1 mA
Accuracy:	± 2% or ± 0.2 mA, which ever greater
Pulse Duration:	0.5 ms, 1-10 ms in steps of 1ms
Accuracy:	± 0.15 ms
Load Impedance:	200-1000Ω, <700 Ω for max current
Max Output Voltage:	27V

viii. Inter-stimulus Intervals

S1 Range:	180 - 9990 ms (Pace) 30 - 9990 ms (Burst Pace)
Stability:	Quartz, ±30 parts per million @ 25° C
Extra-Stimuli:	6 max, S2-S7independent
Coupling interval:	30 - 9990 ms,
Accuracy:	± 1 ms or 0.1% whichever is greater

ix. Patient Interface protection

Circuit Class:	IEC60601-1 Class CF
Defib. Protection:	5kV / 20ms (360J), IEC60601-1
RF Ablation filter:	350 Vp-p/ 200 s, 300 kHz-1 MHz equivalent to RF Ablation energies up to 150W into <= 300 Ohm loads
Input impedance:	>10KΩ (at 500 kHz)
RF protection filter:	Differential: -52dB at 485 kHz, Common Mode: -20dB at 485 kHz

x. Pre-programmed Protocols

- Stimulation Threshold
- Anterograde/Retrograde
- SN Recovery Times
- SN Conduction Times
- His-coincident extras
- Overdrive Pacing
- AICD-type ATP
- Biventricular pacing
- Wenckebach Periods
- Programmed V Stimulation
- Burst Pacing (to 30ms)
- Auto-decremental Pacing
- AV sequential Pacing
- Combined AV drive-train
- AF/VF induction

xi. Protocol Automation

1. Auto decrement / increment: S1, S2-S7,stim current
2. SNRT S1 intervals and RT calculation
3. Auto pace and sense - site selection in protocols
4. His-coincident extra-stimulus timing calculation
5. ATP S1 calculation from % of TCL
6. Trigger output on sensed ectopic beats
7. Stop On Tachycardia
8. All automation subject to instant operator adjustment

xii. Backup Manually Controlled Stimulation

Power Source:	12V 2.1Ah sealed lead acid battery
Pulse Current:	0.1 to 25mA
Accuracy:	± 2%, or ± 0.2mA which ever greater
Pulse Duration:	2ms, fixed
Pulse Interval:	100 - 1400ms, accuracy: ±1%

xiii. ECG Sense/Trigger

High level external -	
Two inputs:	(i) Ext_ECG1, (ii) Ext_ECG2,
Connector:	6.5mm Phone socket
Input Ranges:	±0.5V and ±1.0V pp for FSD
Input Impedance:	47 kOhms
Frequency Range:	1 to 250 Hz, typical
Pacing catheter tip -	
Two channels:	(i) Atrial, (ii) Ventricular
Input ranges:	2mV to 36mV, 4 gains
Frequency Range:	10 to 250 Hz, typical
Either Source -	
Threshold:	Adaptive software peak detect
Lockout Period:	50 - 1000ms in software
Pace Sync Delay:	50 - 5000ms in software
Sampling- display:	500Hz, 8 bit

xiv. Auxiliary Sync Inputs/Outputs

Sync1 Output:	6.5 mm Phone socket
Timing:	On any drive train pulse, on halt of pacing, on extra in R-synced S2
Pulse:	+5V CMOS level, 50 ms duration

xv. Emergency Backup Pacing

Power Source:	9V Lithium Manganese PP3 battery, 10 years life
Pacing Pulse:	5mA ± 1.0 mA, 2ms ± 0.5ms, 100 ± 20 ppm
Pace output:	Separate red Redel 4 pin socket
Control:	Pacing activated by connection of a load <1MΩ, i.e. insertion of plug connected to patient

xvi. Environmental

Operating T° Range:	+5ºC to +35ºC (30% to 80% RH)
Storage T° Range:	-10ºC to +60ºC (10% to 85% RH)
Storage altitude:	0 to 14,000 ft (4267m)

xvii. Certification

MDD Device Class:	Class IIb
CE Marking NB:	0120
FDA Reg. Class/No.:	Class II, 21CFR 870.1750
Health Canada:	Class III
IEC60601-1:	certified
EMC compliance:	certified
US Regulations:	510(k) Cleared

Notes: 1. Specifications may change without notice
2. Computer specifications will vary according to availability

StimLab™ Specifications Ver 1.1, 3.12.07,
Incorporating EPS320 Device Specifications Ver 2.9, 3.12.07
EPS320B-EU/US, PCB Ver P3.14, Sch Ver 3.08

19 STIMULATOR SYSTEM OPTIONAL ACCESSORIES

19.1 Optional Upgrade Installation Kits

Ver 1.2, 19.4.05

Part Number	Description
MP3113	LCD Touch Screen Kit
MP3091	Four Channel Multiplexer Kit
MP3096	StimLink™ Kit for communication with EP Recorder.

19.2 Optional Installation Accessories

Part Number	Description
MP3081	Service Contract per annum, incl. all parts, labor & shipping, software upgrade.
MP3070-08 MP3070-13 MP3070-17	Extension Stim Cable Kit – For Stimulus Connection Box – 8m, 13m, 17m
MP3084-12 MP3084-25	Extension Serial RS232 Cable, (incl. RF suppression) – 12m, 25m
MP3090 MP3146	Extended SM-Box Control Cable - 15m Extended SM-Box Control Cable - 27m

20 GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS

This product complies with EN/IEC60601-1-2.

20.1 Cable Lengths

The following Micropace Cables Comply with:

- RF emissions, EN 55011, Class B/Group 1
- EN 60601-1-2

WARNING: The use of accessories or cables other than those specified may result in increased emission and/or abnormal function of the Micropace Stimulator.

Micropace Part No.	Signal Cables	Length
MP3014	Stimulus Connection Box	2.5m (8.2')
MP3033A	RS232 Boost Serial Cable	2.0m (6.5')
MP3034	ECG Signal Cable	2.5m (8.2')
MP3070-13	Extension Stimulus Cable	13m (42.6')
MP3084	Cable, Extension Serial RS232	12m (39.4')
MP3087	StimLink™ Cable	3 m (9.9')
MP3088	StimLink Mating cable (Serial Modem Cable 25 pin to 9 pin)	3 m (9.9')
MP3089	SM-Box Control Cable (15-15DB)	2.5m (8.2')
MP3090	Extended SM-Box Control Cable (15-15DB)	15m (49.2')
MP3109	BNC to Phone Cable	2.5m (8.2')

Cables included with accessory PC (Personal Computer) and LCD Display comply with their respective manufacturer's declarations.

20.2 EMI / EMC Specifications

- Medical Electrical Equipment needs special precautions regarding Electromagnetic Compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the Accompanying Documents (see below).
- Portable and mobile RF Communications Equipment can affect Medical Electrical equipment.
- Essential Performance: To maintain freedom from unacceptable risk, this equipment has been tested to verify that this Essential Performance is maintained under all conditions specified in the applicable standards.
    - Absence of electrocution hazards
    - Absence of unwanted stimulation
    - Backup stimulation always available
    - Stimulation sequence, synchronization to ECG, timing, and parameters are as programmed.

Guidance and manufacturer's declaration – electromagnetic emissions		
The Micropace Stimulator systems are intended for use in the electromagnetic environment specified below. The customer or the user of the Micropace Stimulator system should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR11	Group 1	The Micropace Stimulator systems uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Micropace Stimulator systems is suitable for use in all establishments, including domestic, and those connected directly to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emission IEC 61000 3-2	Class A	
Voltage Fluctuations / Flicker Emission IEC 61000 3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Micropace Stimulator systems are intended for use in the electromagnetic environment specified below. The customer or the user of the Micropace Stimulator system should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	❑ <5% Ut (>95% dip in Ut) for 0.5 cycle ❑ 40% Ut (60% dip in Ut) for 5 cycles ❑ 70% Ut (30% dip in Ut) for 25 cycles ❑ <5% Ut (>95% dip in Ut) for 5 sec	Complies, no effect Complies, no effect Complies, no effect Complies, no effect	The stimulator SGU is powered by internal backup battery and Essential Performance is maintained when Mains voltage is lost. Mains power quality should be that of a typical commercial or hospital environment. If the user of the Micropace Stimulator system requires continued operation during power mains interruptions, it is recommended that the Micropace Stimulator system be powered from an uninterruptible power supply or external battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
NOTE Ut is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The Micropace Stimulator systems are intended for use in the electromagnetic environment specified below. The customer or the user of the Micropace Stimulator system should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 800 MHz	V1= 3 Vrms E1= 3 V/m	Portable and mobile communications equipment should be separated from the Micropace Stimulator system by no less than the distances calculated/listed below: D = (3.5/V1) √P D = (3.5/E1) √P, 80 MHz to 800 MHz D = (7/E1) √P, 800 MHz to 2.5 GHz where P is the max power in watts and D is the recommended separation distance in meters. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 and 800 MHz, the higher frequency range applies. **NOTE 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Micropace Stimulator system is used exceeds the applicable RF compliance level above, the Micropace Stimulator system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Micropace Stimulator. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the Micropace Stimulator system.			
The Micropace Stimulator system is intended for use in an environment in which radiated RF disturbances are controlled. The customer or the user of the Micropace Stimulator system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Micropace Stimulator system as recommended below, according to the maximum output power of the communications equipment.			
	Separation distance according to frequency of transmitter (m)		
Rated maximum output power of transmitter (W)	150 kHz to 80MHz d = [3.5/3] √P	80 MHz to 800MHz d = [3.5/3] √P	800MHz to 2.5GHz d = [7/3] √P
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.73
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.70	11.70	23.33
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. **NOTE 1** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. **NOTE 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			