



**Contents and
Instructions For Use of the
Four Channel
Stimulus Multiplexer
Upgrade Kit
MP3091 / MP3091L
For EPS320 Cardiac Stimulator**

CAUTION: Federal (U.S.A) law restricts this device to sale, distribution and use by or on order of a physician.

This document describes the contents of the Four Channel Upgrade Kit MP3091 / MP3091L and gives instructions on how to install and use the kit. Please read this document in its entirety prior to installation.

Installation is to be done by qualified representatives of Micropace Pty Ltd or its authorized Distributor.

For use only with Micropace EPS320 Cardiac Stimulators and subject to Warnings and Precautions contained in the EPS320 Cardiac Stimulator User Instruction Manual; please read that document prior to using this product.

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MP Component No: MC3091-1 / MC3091L-1

MP Part: MP3092, SM-Box-Booklet-US-2.0 15.8.05

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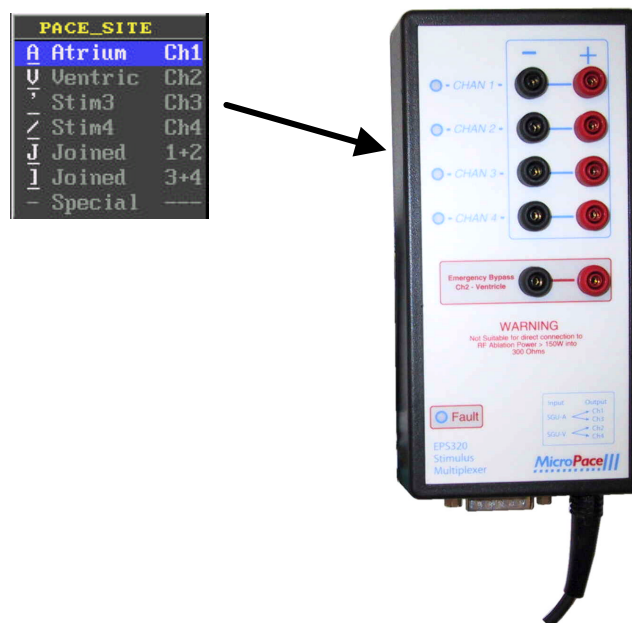
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1. Quick Installation Guide

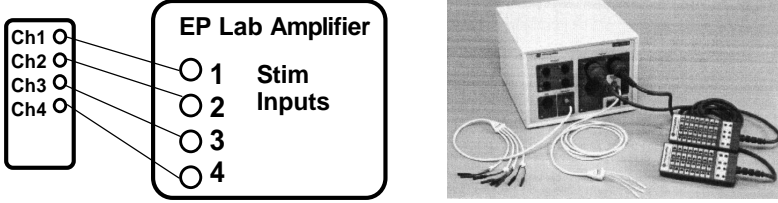
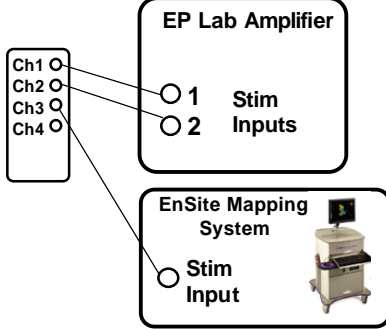
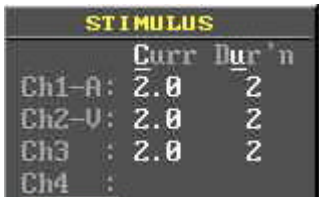
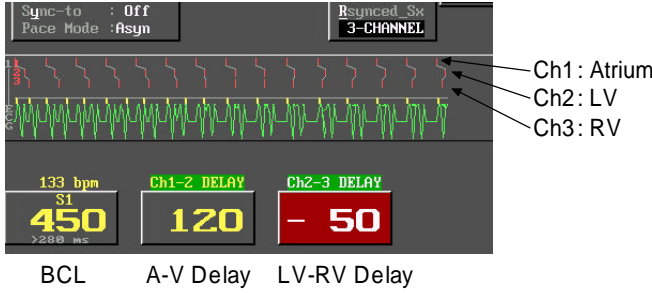
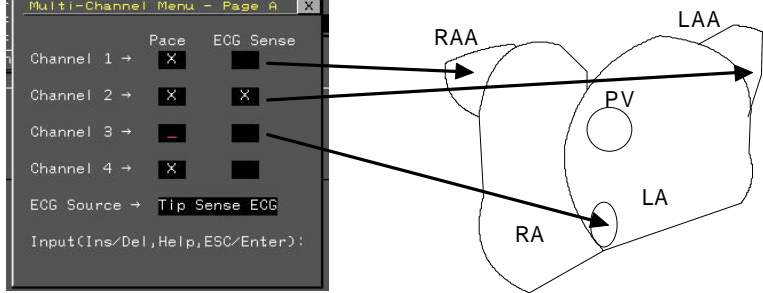
Use this quick installation guide if adding this kit to a newly shipped EPS320B or customer has software Ver 3.19.59 or later, whereby no software upgrade is required.

1. If installing the SM Box near the EPS320, (i) connect the SM Box to SGU's green Stim Output socket on the front, and (ii) to the Auxiliary Port at the rear using the SM-Box Control Cable - MP3089. Refer to Figure 2.
2. If installing the SM Box remote to the EPS320, such as in the patient area, use the optional (i) 12m Extension Stimulus Connection Cable - MP3070 and (ii) the 15m Extended SM-Box Control Cable - MP3090 (instead of MP3089) to make the above connections. The MP3091L kit contains the MP3090 cable as standard.
3. Launch software, invoke Configuration Menu with hotkey 'k' and password 'henry' or 4546, and set Config Service Variable 29 'StimLink & Four Channels' to value '1', or if StimLink™ is also installed then value '3'.
4. Verify correct SM Box installation by rebooting the system – no error messages appear and green lights are present next to Chan 1 and 2; Select Chan 3 – green light moves from Chan 1 to Chan 3, select Chan 4 and observe green light change from Chan 2 to Chan 4.
5. Connect SM Box to the EP Recording system and verify presence of stimulus at selected outputs for each of Chan 1 to 4 using the supplied Test Led - MP3058.
6. Instruct user on use of the SM Box.

Configuration Menu password:	'henry' or 4546
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2. PRODUCT FEATURES

Features / Benefits	Explanation
Compatible with EP Recorder Amplifiers with Four Stim Inputs	
Dedicated third channel for mapping system	
Allows set up of 4 channels with different default currents for rapid changeover between pacing sites	
Special biventricular pacing protocol	
3 or 4 channel near-simultaneous pacing (with Software Ver 3.21+)	 <p data-bbox="965 1809 1289 1863">Advance Atria by multisite pacing to unmask PVP.</p>
Other features	<ul style="list-style-type: none"> <input type="checkbox"/> RF Ablation and defibrillation proof filters <input type="checkbox"/> Emergency Bypass Outputs <input type="checkbox"/> Output and fault indicators for easy maintenance <input type="checkbox"/> Auto-detect by software for easy setup <input type="checkbox"/> Splash Resistant for easy cleaning

3. PRODUCT DESCRIPTION AND SYSTEM REQUIREMENTS

The Micropace Stimulus Multiplexer Box (SM-Box) with EPS320 3.19 or above software system generates 4 stimulus output channels from the EPS320's existing 2 physical stimulus generators by automatic simultaneous reprogramming of stimulus current and pulse duration values are thus seamlessly mapped to outputs Chan1-4. Simultaneous pacing is limited to Chan1+2 or Chan3+4, but not from all four outputs. A unique sequential Three_Channel_Pacing mode is available, delivering stimuli into Chan1 and after a delay into Chan2 and then Chan3, potentially suitable, for example, for biventricular pacing.

This Stimulus Multiplexer Box (SM-Box) Accessory kit may be applied only to EPS320 installations with:

1. EPS320 SGU Firmware Ver. 4.68 or higher
2. EPS320 Software Ver. 3.19 or higher; Software version is displayed in Help (hotkey 'h') / Item: About EPS320

This upgrade kit may be applied to all EPS320 configurations with Software Ver 3.19 or higher and Firmware Versions 4.68 which are present in all Stimulus Generator Units (SGU's) with serial numbers 0101 and higher (for units with Serial No's. 0202 to 0225 contact Micropace for special instructions). It may be applied to all EPS320 units shipped after May 2003, although units shipped May 2003 to April 2004 will require separate software upgrade kits (refer to Section: Upgrade of EPS320 Software).

The Kit contains (i) the four channel Stimulus Multiplexer Box and (ii) required cabling (see Table 2). No software upgrade is required for EPS320 units shipped after April 2004, Ser.No. 241+ and 1050+, which contain the 3.19.59(SR).

Software upgrade is only required if upgrading earlier EPS320 units with initial software releases of Ver 3.19 (=3.19.58) shipped from May 2003 to April 2004. For customers with earlier Software 3.18 or less, a separate upgrade kit will need to be purchased and applied first. Refer to Table 1 for kits which you require and contact your Micropace Distributor or Micropace directly for more information on Firmware / Software Kits.

	EPS320 System	Compatibility
1	New EPS320B System Shipped April 2004+ (Ser.No. 241+ and 1050+)	Fully compatible. Connect SM-Box, change Config Service Var 29 to '1', or if StimLink™ is also installed then value '3' and finish.
2	EPS320B systems with Initial Software 3.19 (=3.19.58) shipped May 03 to April 04	First upgrade software to 3.19.59 (SR) or higher using Software floppy disk and External USB FDD drive or CF card (contact Micropace support@micropace.com.au for this software media). Then attach SM-Box and change Service Var 29 as per instructions in point 1 above.
3	Early EPS320 systems with Software 3.18 shipped before May 03, Ser.No'. < 0250.	For systems with MP3042 Leo Moniputer (non-US countries), a MP3111 Moniputer Upgrade Kit is required. For systems with MP3075 HP eVectra computer, a MP3112 HP eVectra Upgrade Kit is required. Both kits come with the Software Upgrade Kit MP3082-3.20.5 inclusive of firmware upgrade IC and new keyboard. You will need to open the SGU and install a new EEPROM chip; then as per 1 above.
4	Early EPS320 Batch with Serial No's. 0202 to 0225	These have incompatible Auxiliary connectors on the SGU. You will need to open the SGU and replace a connecting cable; then as per instructions in point 3 above. Contact Micropace for special cable and instructions.

Table 1 Summary of SM-Box compatibility

4. WARNINGS AND PRECAUTIONS

Warning:

This product is not a life support device. Use approved temporary pacemaker generators connected directly to intra-cardiac leads for patients requiring life-support pacing.

Warning:

When using the EPS320 Stimulus Multiplexer Box, in order to prevent inadvertent or ineffective pacing, the user should always verify the actual channel being paced using independent Recording Apparatus.

Warning:

Product is not suitable for sterilization.

Precaution:

Always inspect the product prior to use for evidence of damage to the device, associated cables, and connectors; do not use if product appears damaged.

Precaution:

Protect product and cables from ingress of liquids and body fluids. If soiled refer to cleaning instruction section below.

Tools you may need:

For installation onto an earlier EPS320B system (Bona Light PC) with initial Software 3.19.58 release:

- 1) External Floppy Disc Drive (USB) –Micropace Part No.3101, or most available USB drives

For Installation onto early EPS320 systems with serial No. 0202 to 0225:

- 1) Phillips head screwdriver medium size for M3 screws
- 2) Thin nosed pliers
- 3) Drive hex socket or wrench for 5mm nut or a second pair of thin nosed pliers

5. HOW SUPPLIED

The SM-Box kit is supplied with all required components for installation onto the standard EPS320 system. For stimulator installation remote to the patient – such as in a control room, optional Extension Stimulus Connection and Extended SM-Box Control cables will be required.

Stimulus Multiplexer Upgrade Kit- MP3091 or MP3091L ¹		
Item	Part No.	Qty
Stimulus Multiplexer Box (SM-Box)	MP3086	1
SM-Box Control Cable (2m long 15 pin 'D' Con.)	MP3089	1
Instruction Booklet (this booklet)	MP3092	1
Test LED, Yellow/Red	MP3058	1
Optional items (ordered specifically):		
Extended SM-Box Control Cable (15m)	MP3090	1
Extension Stimulus Connection Cable (12m)	MP3070	1

Table 2 MP3091 Kit Contents

Note1: The **MP3091L** kit variant comes standard with the MP3090 Extended control cable.

5.1 MP3086 Stimulus Multiplexer Box

This connection box provides stimulus outputs.

A Stimulus Extension Cable (MP3070) obtained from Micropace may be used with the Stimulus Connection Box. Refer to the Installation Procedure.

Emergency Bypass: In case of real or apparent failure of the Stimulus Multiplexer Box, and need for urgent pacing, use Emergency Bypass Feature on front panel, ensuring that you set the software to pace Ch2-Ventricle or use the Emergency Pace (F12) protocol.



Figure 1 The Stimulus Multiplexer Box

Warning: Use only supplied SM-Box (Micropace Part MP3086) or Stimulus Connection Box (MP3014) or alternative optional In-line RF Filter (MP3065) components to connect Stimulator 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.

5.2 MP3089 SM-Box Control Cable

This cable provides control communication connection between the SGU's Auxiliary port and the SM-Box. It is a straight through DB15 pin cable. The MP3090 is an extended 15m version.

5.3 MP3058 Yellow/Red Test LED

This is a helpful test jig consisting of a yellow and a red LED wired in parallel and terminated in a red(+ve) and a black(-ve) 2mm banana plug. It may be useful in testing for the presence of stimulus output at the Stimulus Multiplexer Box or at the patient interface connector. Connect red plug to positive and black plug to negative pacing output terminals. Pace at 10mA to 20mA for brighter indication. Yellow LED flashes when pacing with correct polarity; red LED flashes when pacing but with incorrect polarity.

This is intended for testing system installation and as an aid to diagnosing the location of faults when a failure to pace problem arises. See Installation Procedure document and troubleshooting section of User Instruction Manual.

6. OPTIONAL ITEMS

6.1 *MP3090 Extended SM-Box Control Cable (optional)*

This cable is a 15m (49-foot) extension cable connecting between the SGU Auxiliary port and the SM-Box control input port. It is a straight through DB15 pin to DB15 pin cable. It is included as standard in the MP3091L kit variant.

6.2 *MP3070 Extension Stimulus Connection Cable (optional)*

This cable is a 12m (39-foot) extension cable connecting between the SGU Stimulus Output Connector and the SM-Box Stimulus connector. All connectors are colored green for easy identification.

This cable may be used in conjunction with the Extended SM-Box Control cable to locate the SM-Box remotely from the EPS320, typically next to the patient bed when the EPS320 is in the control room.

7. INSTALLATION INSTRUCTIONS

Installation steps include:

1. Upgrade of EPS320 Software
2. Interconnection of hardware components
3. Connections to and configuration of EP Recording equipment
4. Configuration of EPS320 Software
5. Verification of System Function.

7.1 Upgrade of EPS320 Software

Minimum required software version is 3.19.59. If you are upgrading to four channels with a newly shipped EPS320B system, you do not need to upgrade software, as it will have software version 3.20 or above; please skip this section and proceed to Section 7.2.

If you are upgrading systems with earlier software than 3.19.59, then you will need one of the following upgrade kits:

Existing system	Upgrade Kit
EPS320 (Moniputer)	MP3111, Moniputer Upgrade Kit
EPS320H-EU or US (HP eVectra)	MP3112, HP eVectra Upgrade kit
EPS320N-US (NEC Powermate)	MP3111, Moniputer Upgrade Kit
EPS320B-EU or US (Bona PC) with software version 3.19.58	Contact Micropace for software upgrade media.

Table 3 Software Upgrade Matrix

Contact Micropace by email support@micropace.com.au for further information.

7.2 Interconnection of hardware components

Connect Stimulus Multiplexer Box (SM-Box) to the Stimulus Generator Unit (SGU) as shown in Figure 2. Insert the green four pin plug into the green stimulus output socket on the front of the SGU and use the SM-Box Control Cable (MP3089) to interconnect the 15 pin socket on the SM-Box to the 15 pin Auxiliary Port on the rear of the SGU. Ensure connectors are attached and secured with jackscrews.

If the SM-Box is required to be located remotely to the SGU, use the optional MP3070 Extension Stimulus Connection Cable, available from Micropace, and the MP3091L kit variant containing the extended 15m MP3090 Control cable, or if you have the standard MP3091 Kit, order the MP3090 cable separately.

The SM-Box requires connection of two shrouded 2mm banana plugs for each channel.

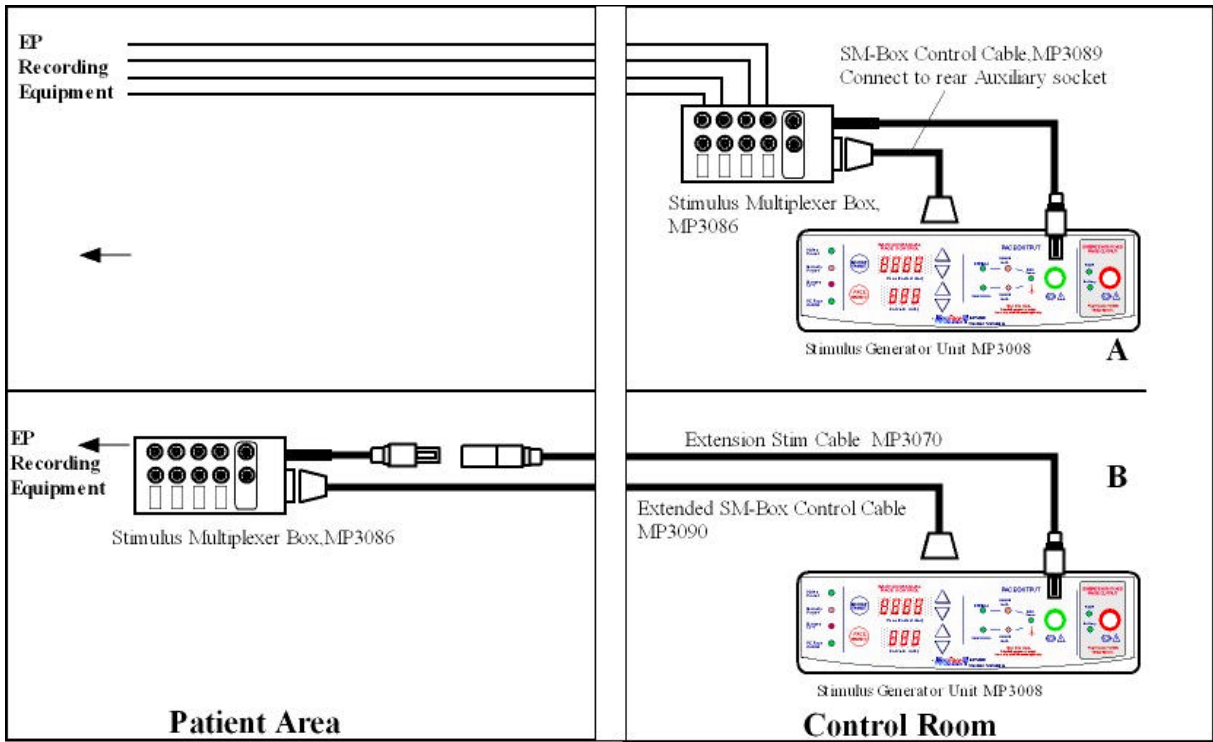


Figure 2 Interconnecting the SM-Box

7.3 Connections to and configuration of EP Recording equipment

The four output ports may be connected directly to inputs of a four channel recording / switching equipment. If your recording equipment has only two input channels, you may connect channels 1 and 2 to the recorder/switching equipment and channels 3 and 4 to stim inputs equipment such as 3D mapping systems or directly to multi-pole catheters via standard electrical catheter extension leads.

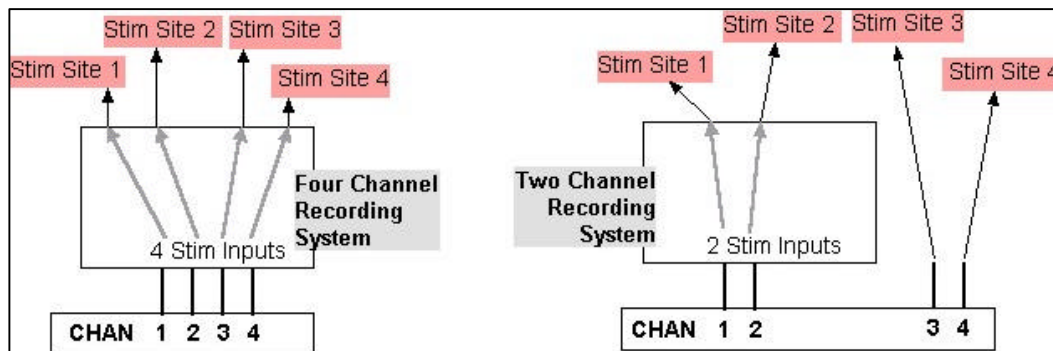


Figure 3 Connecting the SM-Box to Recorder equipment - Four and two channel versions.

7.4 Configuring the EPS320 Software

Launch software as per EPS320 User Instruction Manual. Edit the Service Configuration Menu (hotkey 'k' password: henry, then PGDN, password: Service) Variable 29 'StimLink & Four Channels' to value '1', or if StimLink™ is also installed then value '3'. Focus on variable 29 with arrow keys and press 'h' to obtain help text if necessary. If SM-Box is not connected or software not configured for the SM-Box as above, then a message will appear informing you of the problem and how to rectify it.

7.4.1 How the SM-Box works

The four channel Stimulus Multiplexer Box accepts the two physical output channels of the EPS320 SGU and switches them under the control of the EPS320 software to one or two of the four output ports. Channels 1-4 and their output current and pulse width values on the software interface are seamlessly mapped to Output ports 1-4. Simultaneous pacing from Chan 1+2 or Chan 3+4 is possible, but not from all four outputs. A unique Three_Channel_Pacing mode is available, delivering stimuli into channel 1 and after a delay into channels 2 and 3, potentially suitable for example for biventricular pacing.

The EPS320 / SM-Box combination thus overcomes the limitation of only two physical SGU stimulus generators by redirecting Hardware channel 1-Atrium to either Outputs 1 or 3 and hardware channel 2-Ventricle to outputs 2 or 4, with appropriate reprogramming of stimulus parameters.

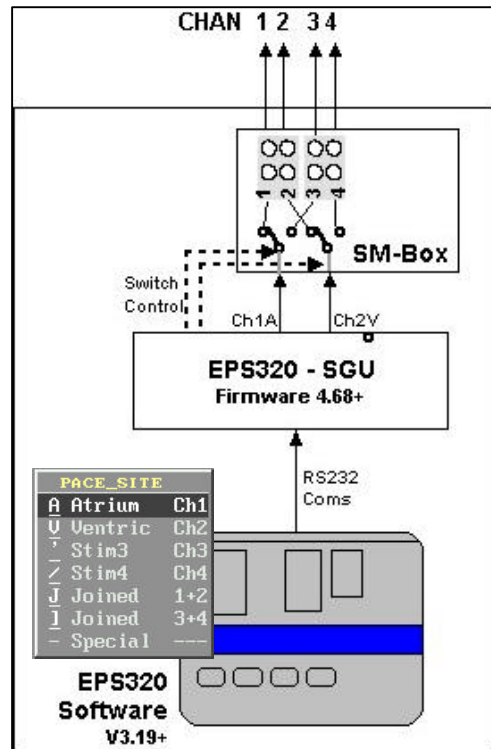


Figure 4 Internal function of the EPS320–SM-Box combination.

7.5 Verifying SM-Box Function

Verify first the SM-Box function and then the entire installation, making use of the supplied Micropace MP3058 Test LED to ensure stimulus is produced where expected.

7.5.1 EPS320 Setup:

- 1) Install SM-Box fully as described above.
- 2) Set EPS320 to pace Ch1-Atrium at 25mA
- 3) Insert MP3058 Test LED into SM-Box Chan 1 output
- 4) Start pacing and observe
- 5) Set EPS320 in turn to pace into Ch 2, 3 and 4 at 25mA, moving the Test LED to Output Chans 2, 3 and 4.

7.5.2 Observe:

- 1) Output Chan 1 and Chan 2 should have green indicators lit next to them
- 2) Fault Indicator should always remain off (its function is duplicated by EPS320 software message)
- 3) Paced output Chan should have a green indicator lit and the Test LED should light with each stimulus. (Test LED functionality described above in Section 5.3)

7.5.3 EP System

- 1) Connect EPS320 / SM-Box to the EP recording equipment.
- 2) Configure EP recording equipment to output stimulus into outputs used for High Right Atrium.
- 3) Insert the Test LED into the bedside EP recorder's stimulus connection box.
- 4) On the EPS320 Pace into Ch1–Atrium, using 25 mA and 10ms Duration,
- 5) Verify that Test LED lights.
- 6) Repeat pacing into other commonly used stimulation configurations and verify Test LED lights.

8. CUSTOMER TRAINING

In order to ensure safe use of this product and reduce customer calls for support, the customer should be instructed in the following items:

- 1) Safety Warnings and Precautions at the beginning of this document
- 2) Safety Warnings and Precautions in the EPS320 Cardiac Stimulator User Instruction Manual
- 3) How to select Pacing output channels 1 to 4 on the EPS320 and how to configure the EP Recorder system to accommodate these channels.
- 4) How to verify the functioning of the SM-Box – EP recorder system.
- 5) Use of the Emergency Bypass output sockets in case of SM-Box failure.

9. TROUBLESHOOTING THE INSTALLATION

1. Software is not detecting SM-Box although two green LEDs on the SM-Box are lit:
 - (i) Ensure that Config-Service-Var29 is set to 1.
 - (ii) Exit and restart EPS320 software.

2. Software is not detecting SM-Box and no green LEDs on the SM-Box are lit:
 - (i) Ensure that the SM-Box Control Cable (MP3089) or Extended control cable (MP3090) is connected securely to both the SM-Box and the SGU Auxiliary Port (DB15).
 - (ii) If the SGU has a Serial Number between 0201 to 0225, then the SGU is likely to have an incompatible Auxiliary Port. This incompatibility is due to a missing wire in the DB15/ribbon cable assembly in the SGU, and this can be readily replaced in a service center, using special cable assembly MP3202 and instructions – contact Micropace.
 - (iii) If problem persists, either the SM-Box or the SGU may be faulty – contact Micropace.

3. Any of the following events indicate likely failure of the SM-Box:
 - (i) Red Fault indicator lights on SM-Box.
 - (ii) Fewer or more than two green Active Channel indicators are lit.
 - (iii) EPS320 Software message appears indicating SM-Box not functional.
 - (iv) Stimulus fails to be delivered as expected (configurational errors in all equipment in the stimulus circuit need to be excluded first).
 - (v) Green Channel LED's on SM-Box do not change when switching on EPS320 software between Stim Chan1 and Chan3.

10. USING THE FOUR STIMULATION CHANNELS

The SM-Box has a number of important features explained below.

10.1 Stimulus Multiplexer (SM-Box) features

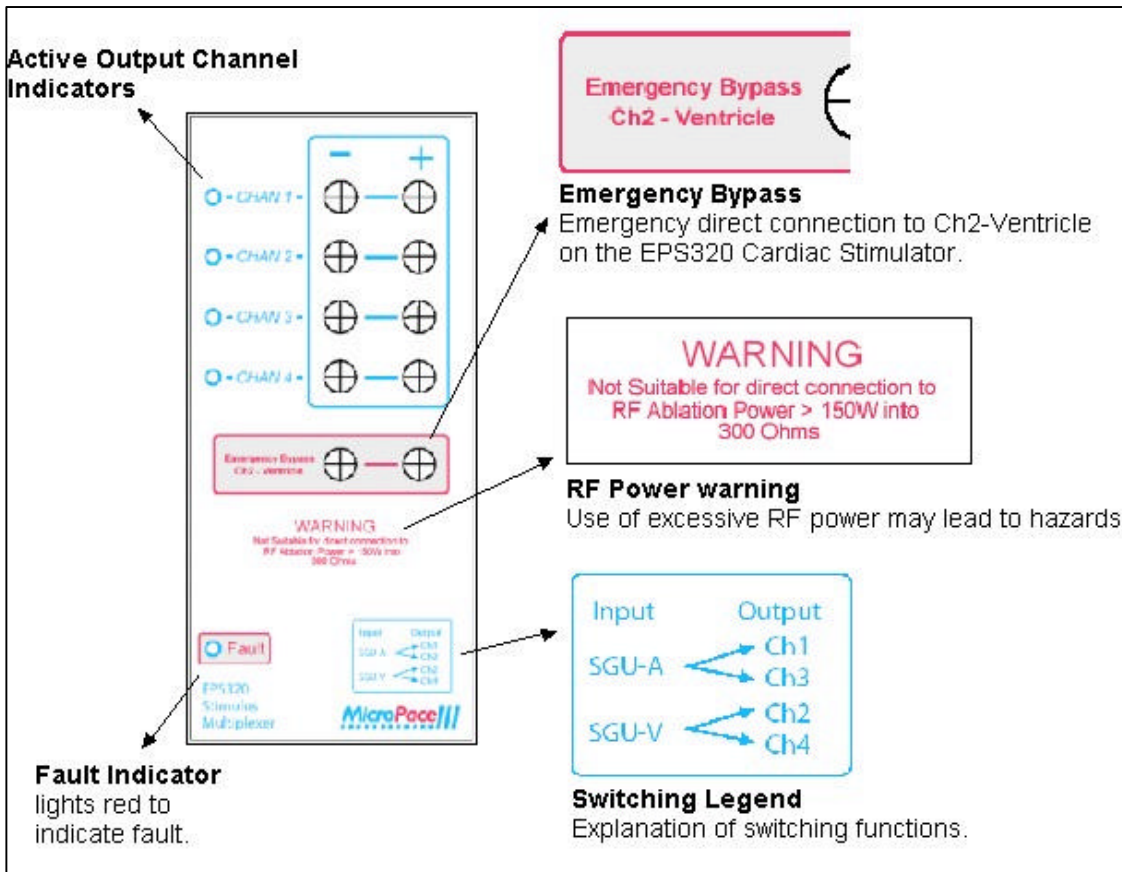


Figure 5 Details of the SM-Box decal labelling

10.1.1 Active Output Channels Indicators

Two green indicators light next to the active output channels. In the 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.

10.1.2 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 EPS320 Software Ver 3.19 or above, will display a message to that effect, if software is configured for the SM-Box.

10.1.3 Switching Legend

This indicates the switching function of the SM-Box. The EPS320 Stimulus Generator Atrium output is switched to either output Ch1 or Ch3 and Ventricle into Ch2 or Ch4.

10.1.4 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.

10.1.5 Emergency Bypass

This is an emergency direct connection to Ch2-Ventricle on the EPS320 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 EPS320. 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.

10.2 Software Support

In the EPS320 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. Refer to the User Instruction Manual for EPS320 Software Ver. 3.19 or above, for more details.

Refer to Figure 5 for explanation of the features on the SM-Box.

PACE_SITE		
A	Atrium	Ch1
V	Ventricle	Ch2
'	Stim3	Ch3
/	Stim4	Ch4
J	Joined	1+2
I	Joined	3+4
-	Special	---

Figure 6 Pace Site Software Menu

11. CLEANING, MAINTENANCE AND SERVICE

- ❑ Do not open the Stimulus Multiplexer Box; it contains no user serviceable parts. Contact Distributor for product service.
- ❑ Product is not suitable for sterilization.
- ❑ The EPS320 Stimulator should be kept clean to ensure reliable operation.
- ❑ Protect product and cables from contamination with or ingress of liquids or body fluids.
- ❑ Product and associated cables 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.
- ❑ Inspect the equipment once a month thoroughly for evidence of damage to the device, associated cables, and connectors; do not use if product appears damaged.
- ❑ Product does not require calibration.

12. Appendix A – SPECIFICATIONS

Absolute Maximum Parameters

Maximum output over-voltage (10ms pulse): 5kV

Maximum output over-voltage pulse current (10ms pulse): 15A

Output Isolation (to circuit ground) 5kV rms

Parameter ^(Note3)	Min	Max	Units
1. Input stimulus channels			
Input Signal amplitude	-47.0	+47.0	V
Input Current (pulse)		15	A
Series Resistance (Outputs shorted, for any channel)	3.6	5.5	Ohms
Series Inductance (Outputs shorted, for any channel)	27	59	mH
2. Input controls (Control1/2)			
High threshold	3.0		V
Low threshold		0.6	V
Input Current (Vin = 4.3V)		1.5	mA
3. Output stimulus channel			
Maximum working applied voltage ^{Note1} (DC)		+/-45	V
Maximum working applied voltage (300kHz – 500kHz) ^{Note2}		350	Vp-p
Output shunt capacitance	8	18	nF
Maximum continuous current		300	mA
4. Output Fault signal			
High (Vcc 4.5V, Io 4mA)	4.0		V
High (Vcc 5.0V, Io 20uA)	4.9		V
Low (Vcc 4.5V, Io 4mA)		0.25	V
4. Fault-TP1/2			
Low (Test Fault Diagnostic Circuit), resistance to GND		< 8	Ohms
High (Normal operation)	10,000		Ohms

Note 1: Voltage tolerated without clamping

Note 2: Produced by EP RF Ablation Generators at 150W into up to 300-Ohm loads

Note 3: Parameters are characterized by design

The revision number of this document is on the title page at the bottom. Refer to the User Instruction Manual and any supplements therein for the latest revision number and / or supplemental information.

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