EPS320 Series Cardiac Stimulators

Stimulus Generator Unit

Field Calibration Check Procedure

V1.4 26 June 2009
For Models EPS320B, EP320BT, StimLab™, ORLab™

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EPS320B EPS320BT StimLab™ ORLab™

Contents

1. Purpose:

This procedure is for the checking in the field of the function and calibration of the Stimulus Generator Unit for the EPS320 Series of Cardiac Stimulators.

2. Scope

This Test Protocol applies to Micropace EPS320 Series of Cardiac Stimulators, Models EPS320B, EPS320BT, StimLab™ and ORLAb™, with their respective application software and with stimulus generator units (SGU) serial numbers 300+ (PCB Ver 3.8 and above). Variances in acceptance ranges for earlier serial numbers are noted in footnotes. The tests concern principally the performance of the SGU which generates the stimulation pulses.

The test is optimally performed with the PC connected and application software operational for easy programming of the required stimulus outputs. A subset of the tests (Items 2, 9, 11 and 12) may however be applied only using the SGU, if the computer with software is not available, as the SGU may be operated in the Manual Backup mode.

3. Glossary and Terms

SYMBOL	EXPLANATION
CH1	Atrium channel on Patient box
CH2	Ventricle Channel on Patient box
CMOS	Complementary Metal Oxide Semiconductors
CPU	Central Processing Unit
DVM	Digital Volt Meter
FSD	Full scale deflection
ECG:	Electrocardiogram
IECG:	Intracardiac Electrocardiogram
LED	Light emitting diodes and seven segment displays when referring to display information
PC	Personal computer, IBM compatible
POST	Power On Self Test
PW	Pulse Width of stimulus (Duration on EPS320 interface)
SGU:	Stimulus Generator Unit – the EPS320 unit which produces stimuli
UIM	User Instruction Manual
µP	Microprocessor, in this manual refers specifically to the PIC16C77 micro-controller, by Microchip
BCP	Balanced Charge Pacing – circuit in SGU which neutralizes charge build-up
PCB	Printed Circuit Board

4. Field Calibration Testing

Full EPS320 specification verification is beyond the scope of customers. Should SGU performance need to be verified in the field, the following test procedures verify the safe and efficacious functioning of the stimulator.

Acceptance ranges of some parameters are wider than per published specifications because of the limited accuracy and precision inherent in field equipment (eg. measuring inter-stimulus interval of 900ms to 1ms is not feasible with a normal oscilloscope).

4.1 Test Items to measure in Field Calibration Test:

Use Calibrated measurement test equipment only.

1. PC bootup, POST and keyboard response.
2. SGU POST
3. Computer Link Port integrity
4. Stimulation channel output Atrium (Ch1): zero, minimum, middle and maximum current outputs and minimum and maximum pulse durations, into 1kOhm.
5. Stimulation channel output Ventricle (Ch2): as per Atrium above.
6. Pulse inter-stimulus interval at 100ms and 900ms.
7. External ECG sensing
8. Internal ECG sensing
9. Backup Pacing pulse amplitude, pulse duration and inter-stimulus interval
10. Emergency Fixed Rate Pacing pulse current amplitude, inter-stimulus interval and Battery status indication.
11. Backup and Emergency Battery Charge –direct
12. IEC60601-1 Patient safety parameters
13. Four Channel Stimulus Multiplexer Box function
14. Touch Screen calibration.
15. BCP (Balanced Charge Pacing) Test

4.2 Equipment required:

1. 1.00 kOhm 0.1% 0.25W resistor
2. 6.5mm mono or stereo phone plug
3. 2mm banana plugs (4 of)
4. 9V PP3 style battery and clip
5. 10kOhm 1% 0.25W resistor
6. Calibrated 20MHz or better Oscilloscope
7. 0-2 Vpp 10Hz sine wave signal source
8. Adjustable 0-50mVpp 5-20Hz signal source, <= 1kOhm source impedance
9. IEC60601-1 Medical Equipment Safety Tester

4.3 Test Procedure

Use the following procedure / worksheet:

Tester Name:	
Date:	

Test Item / Procedure	Expected Result	Observed Result	OK
1. PC boot-up, POST and keyboard response			
1.1 Interconnect Stimulator system components according to UIM, i.e. connect PC to keyboard, monitor and power supply, connect SGU to PC and to its power supply and plug in the 2 (or 4) channel Stimulus Connection Box (4 chan box requires a control cable to SGU Auxiliary port).			
1.2 Switch on the PC and observe for any error messages.	1.2 EPS320/StimLab/ORLab main screen appears with “Looking for SGU…” message	1.2)	
2. SGU POST 2.1 Switch on SGU and expect following sequence of messages on the SGU’s two LED Displays: [ ] [ ] Nothing, which together with the lit green MAINS POWER LED, indicates the Standby Mode. Within seconds, the PC connects to the SGU clearing its own “Looking for SGU message” , and the SGU display shows the following: [PC] [ ] indicating the PC Pace Controlled mode, indicated also by a green PC PACE CONTROL LED. Press 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, [8888] [888] all segments test, [EPS] [320] indicating the model of the device, [VEr] [4.68] indicating the firmware version, [BAtt] [15.5] indicating battery voltage, and finally, [600] [5.0] indicating the default pacing interval and pacing current in the Backup Manual Pace Mode.	2.1 Sequence of LED display messages as shown in procedure. Firmware VEr may be: 4.53, 4.68, 4.69, 4.73	2.1)	

Test Item / Procedure	Expected Result	Observed Result	OK
3. Computer Link Port integrity The PC should now display a message asking if you want to reconnect to the SGU. Accept to reconnect; SGU should then display PC [ ] indicating entry into PC mode.			
Select Burst Pace Menu. Set S1 to 200ms			
4. Stimulation channel output Atrium (Ch1) Connect 1kOhm resistor across Atrium Ch1 output and measure voltage across this resistor with oscilloscope. 4.1 Zero output state - Leaving pacing off, measure the voltage across the resistor	4.1 <= 0.01V	4.1)	
4.2 Set up Stimulus for Atrium Channel to PW: 10ms, Current: 0.1mA, Burst Pace Protocol, S1: 100ms start pacing. Set oscilloscope to 0.1V/div, 2.5ms/div on triggered sweep and 'find' the 0.1V 10ms pulse (may be difficult among 50Hz noise – in which case remove any nearby mains equipment).	4.2 Pulse: Width: 10ms ±0.2ms Amplitude: 0.1V ± 0.02V Interval: 200ms ±2ms Refer Figure 1	4.2)	
4.3 Repeat 4.2 with Stim current set to 5mA and Oscilloscope set to 1V/div	4.3 Pulse: 10ms ±0.2ms 5.0V ± 0.2V <=25% overshoot Refer Figure 2	4.3)	
4.4 Repeat 4.2 with Stim current set to 20mA and Oscilloscope set to 5V/div	4.4 Pulse: 10ms ±0.2ms 20.0V ± 0.5V <=25% overshoot Refer Figure 3	4.4)	
4.5 Repeat 4.2 with Stim current set to 5mA and PW of 0.5ms and Oscilloscope set to 1V/div and 500us/div	4.5 Pulse: 0.5ms ±0.2ms 5.0V ± 0.2V Refer Figure 4	4.5)	

Test Item / Procedure	Expected Result	Observed Result	OK
5. Stimulation channel output Ventricle (Ch2) Move 1.00 KOhm resistor to Ventricle Ch2 and repeat items 4. above for Ventricle Channel. Refer to corresponding Figures.	5.1 <= 0.01V 5.2 Pulse: PW: 10ms ±0.2ms Ampl: 0.1V ±0.02V Interval: 200ms ±2ms 5.3 Pulse: PW: 10ms ±0.2ms Ampl: 5.0V ± 0.2V <=25% overshoot 5.4 Pulse: PW: 10ms ±0.2ms Ampl: 20.0V ± 0.2V <=25% overshoot 5.4 Pulse: PW: 0.5ms ±0.2ms Ampl: 5.0V ± 0.2V	5.1) 5.2) 5.3) 5.4) 5.5)	
6. Pulse inter-stimulus interval at 100ms and 900ms. In models other than ORLab™, select Configuration with ‘k’ hotkey, password ‘henry’ and note value of Parameter and then change it to 100ms (remember to restore at end) Leave stimulator on Ventricle, Burst Protocol, Current 5mA and S1: 100ms. Ensure PW (Duration) is 2ms. 6.1 Set Oscilloscope to 1V/div at 25ms/div and measure inter-stimulus interval 6.2 Set S1:900 ms and Oscilloscope to 1V/div at 200ms/div and measure inter-stimulus interval	 6.1 100ms ± 2ms 6.2 900ms ± 10ms	 6.1) 6.2)	

Test Item / Procedure	Expected Result	Observed Result	OK
7. External ECG sensing Set up Signal generator to 1V pp sine wave at 10Hz; insert 6.5mm Phone plug into ECG1-Input on the rear of the SGU; connect active signal to centre pin, signal ground to barrel of connector. (NB this circuit is ground referenced).			
7.1 For ORLab™: Set In Administration Setting Page parameter "ECG Monitor Gain" to 1000 Set scale on top channel-SECG to 25mm/mV Measure physical height of sine wave peak to peak Next go to 8. below	7.1 Sine wave 25mm high ±30%	7.1)	
7.2 For EPS320B, EPS320BT, StimLab™: Select Ext1_ECG on Stimulator with hot key Alt-1 and open QRS Detect menu (hot key Alt-Q) and Select Ext1 ECG gain: 1x. Observe sine wave in QRS Detect window.	7.2 Sine wave signal 50% ±30% height of window	7.2)	
7.3 Repeat 7.2 with Gain at 2x	7.3 Sine wave signal 100% ±30% height of window	7.3)	
7.4 Repeat 7.2 and 7.3 for other input channel: Change Phone plug to ECG2_Input; press Alt-2 and select Gain back to 1x	7.4 Sine wave signal 50% ±30% height of window	7.4)	
7.5 Change gain to 2x and repeat 7.4	7.5 Sine wave signal 100% ±30% height of window	7.5)	

Test Item / Procedure	Expected Result	Observed Result	OK
8. Internal ECG sensing Disconnect 1.00Kohm load from all Outputs and plug two 2mm banana plugs into Atrium Chan1 outputs, Connect 0 to 50mVpp 20Hz <= 1kOhm source impedance signal source to these plugs. 8.1 For ORLab™ Adjust signal amplitude on source to 5mV Set Scale on Display Chan2: IECG1 to 5mm/mV Measure physical height of displayed sine wave 8.2 Repeat 8.1 for IECG2 Next go to 8. below 8.3 For EPS320B, EPS320BT, StimLab™: Select Atrium Sense site, with hot key Alt-A, and set gain in QRS Detect window to 2x. Set signal source to 9mVp-p. Observe sine wave in QRS Detect window. 8.4 Change banana plugs to Ventricle Ch2, select sensing from Ventricle with Alt-V and repeat for 8.3. Note: other gains are unlikely to be incorrect but may be tested proportionally.	8.1 Sine wave on IECG1 is 25mm high ±30% 8.1 Sine wave on IECG2 is 25mm high ±30% 8.3 Sine wave occupies 100% ±30% of window. 8.4 Sine wave occupies 100% ±30% of window.	8.1) 8.2) 8.3) 8.4)	
9. Backup Pacing pulse amplitude, pulse duration and inter-stimulus interval Connect 1.00 KOhm resistor into Ventricle Chan2 and measure voltage across it with Oscilloscope set at 1V/div, 100ms/div Triggered. Press Backup Enable on SGU. Set Pacing Interval to 300ms and leave Current on 5mA. Press PACE. 9.1 Observe Atrium and Ventricle LEDS 9.2 Observe Check Catheter LED's 9.3 Measure pulse height, width and interval.	9.1 Both LED's light 9.2 Atrium Check Catheter lights only 9.3 5.0mA ± 0.2mA 2.0ms ± 0.2ms 300ms ± 2%	9.1) 9.2) 9.3)	

Test Item / Procedure	Expected Result	Observed Result	OK
10. Emergency Fixed Rate Pacing Unplug Stimulus Connection Box green plug and plug into red Fixed Rate Emergency Pace socket. Ensure 1.00Kohm resistor is present in Ventricle Ch2 outputs and measure Voltage across it as per 9. above. 10.1 Observe LED's 10.2 Measure pulse height (at peak), pulse width and inter-stimulus interval.	10.1 Batt Good LED lights after 3-8 sec; Pace V lights with each pulse 10.2 Pulse measures 5.0mA ± 1.0mA 2.0ms ± 0.7ms 600ms ± 100ms	10.1) 10.2)	
11. Backup and Emergency Battery Charge – direct Remove SGU cover by unscrewing 7 Phillips screws at the rear. 11.1 Measure voltage on 9V PP3 style battery	11.1 >= 8.6V	11.1)	
12. IEC60601-1 Patient safety parameters 12.1 Ensure all EPS320 system components are energised through the Micropace or similar Medical grade Isolation transformer. 12.2 Use commercial IEC / UL60601-1 tester to verify isolation of Class CF Applied body parts (Channels Atrium and Ventricle and Ch3 and 4 if present), earth leakage currents, enclosure leakage current and single fault applied part and enclosure leakage currents as per IEC60601-1. If above instrument is not available, the following steps can be used to obtain an indication of likelihood but not proof of the integrity the Class CF patient circuit isolation barrier: 12.3 Connect a calibrated Megger insulation tester (500V or 1000V) between Atrium Chan1 output pins, singly or joined together and the SGU Chassis. Test insulation. Repeat 12.3 for Vent Ch2	12.1 IEC60601-1 tests all pass 12.2 >200Mohm resistance 12.3 >200Mohm resistance	12.1) 12.2) 12.3)	
13. Four Channel Stimulus Multiplexer Box function 13.1 Set Channel 3, Current 5mA, Duration 2ms, Burst protocol S1: 300ms. Oscilloscope on 1V/div 300ms/div, Auto. Observe LED next to CH3 lights and measure pulses. 13.2 Repeat 13.1 for Ch4.	13.1 5.0Vpp ± 0.2Vpp, LED lights 13.2 5.0Vpp ± 0.2Vpp, LED lights	13.1) 13.2)	

Test Item / Procedure	Expected Result	Observed Result	OK
14. Touch screen Calibration For systems with Touch Screen: 14.1 For ORLab™ select on Current Study Page the Setup Spanner icon and then select Cross-hairs icon to enter Touch Calibration mode. 14.2 For EPS320B/BT, StimLab™ Select Help / Touch Calibrate (Soft Ver 3.21) or Help / Setup / Trigg Calibrate (Soft Ver 3.20). 14.3 Follow instructions on the screen, touching the screen accurately on indicated crosses.	14.3 Touch calibration completes	14.3)	

4.3.1 Summary:

All items must pass for System to pass, with the exception of 12.1, where an IEC60601-1 tester is not available.

5. Figures

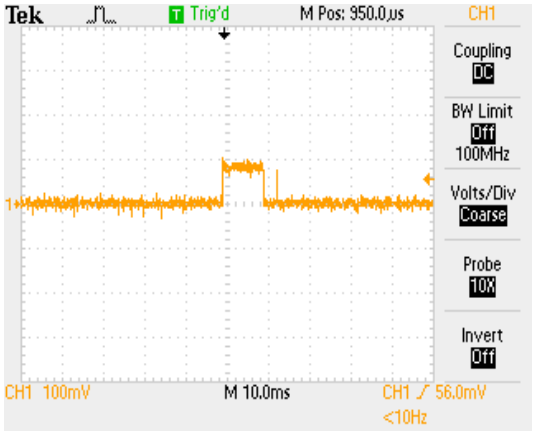


Figure 1 Test 4.2 – 0.1mA pulse

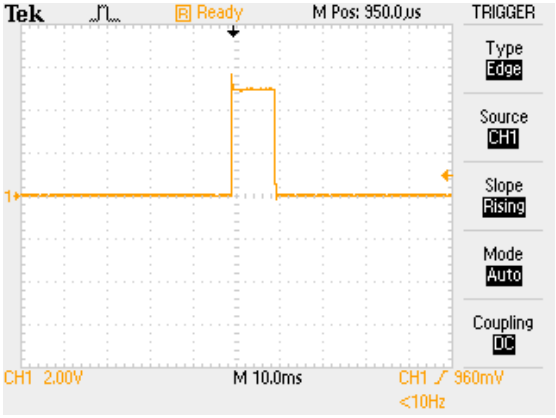


Figure 2 Test 4.3 - 5mA pulse

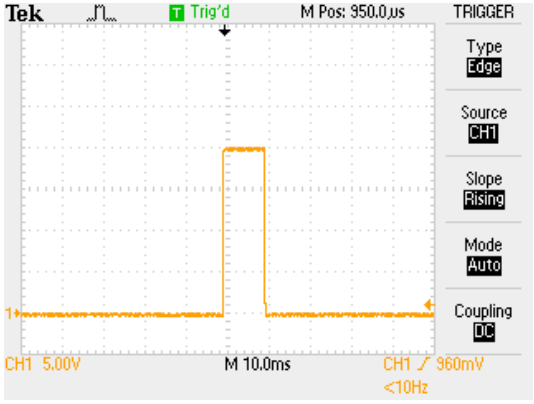


Figure 3 Test 4.4 – 20mA pulse

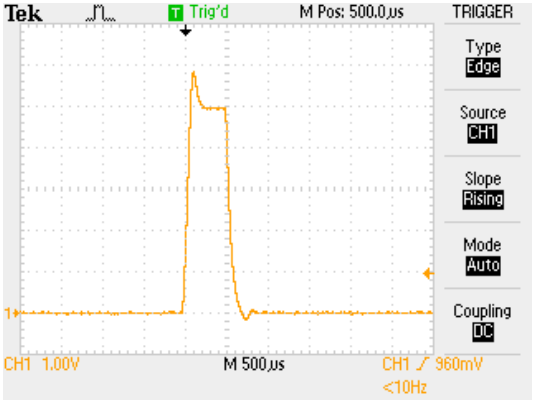


Figure 4 Test 4.5 – 5mA 0.5ms Pulse

6. Verification of Balanced Charge Pacing

This BCP output conditioning circuit reduces the catheter charge build up, especially during rapid pacing with high current amplitudes. It achieves this by shorting the stimulator channel for a period of time after the stimulus pulse and maintaining an output impedance of 10kOhms between pulses.

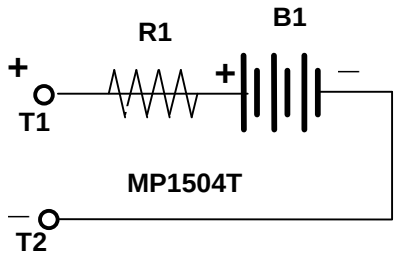
The function of this circuit is not required for the nominal functioning of the EPS320 stimulator. The circuit may enlarge the stimulus artifact itself, but helps to reduce IECG amplifier saturation during rapid pacing; any malfunction of the circuit reduces this benefit.

If the customer is experiencing unusually large amplifier saturation during pacing, then this circuit may be tested by this procedure.

6.1 Equipment:

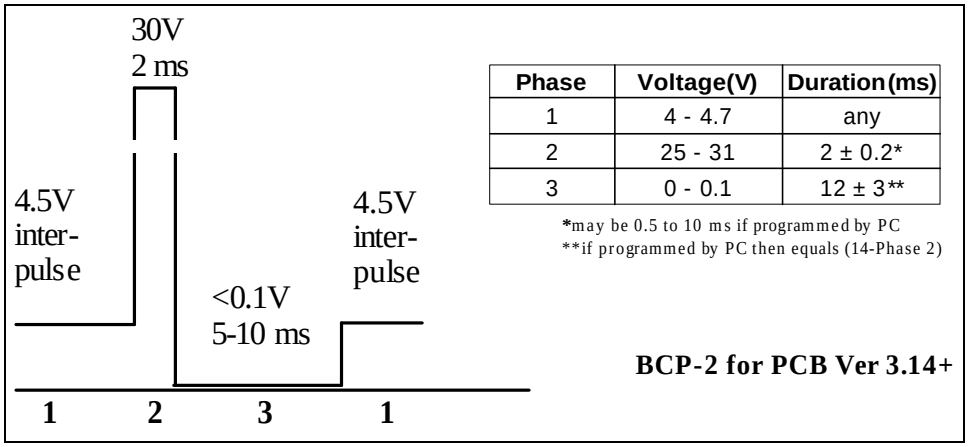
Make test component MP1504T, with a PP3 9V battery clip with R1: 10 kΩ 0.5W 1% resistor wired in series with the +ve battery terminal, and both terminals terminated with 2mm banana plugs (red for +ve, black for –ve). A loop of wire should protrude from the back of each 2mm plug to allow CRO test lead connection.

The MP1504T circuit:



6.2 Test Procedure

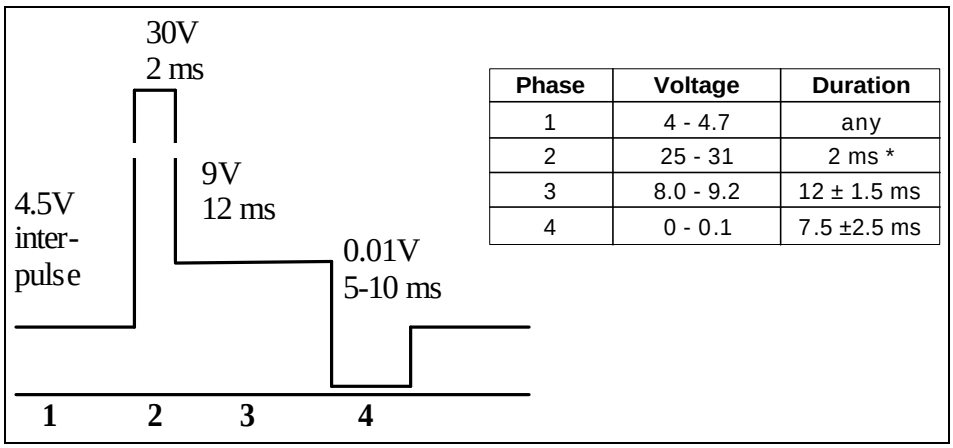
Test Item / Procedure Balanced Charge Pacing Test	Expected Result	Observed Result	OK
15.1 Set SGU into Backup mode by pressing **BACKUP ENABLE**, and set **Pace Interval** to 600 ms and **Current** to 5.0 mA. Press **PACE ON/OFF** to start pacing. 15.2 Connect +ve and –ve output terminal of MP1504T test jig to the Stimulus Connection Box +ve and –ve patient outputs of **Chan1-ATRIUM** terminals respectively. 15.3 Connect Oscilloscope set to 2V/div and 5ms/div across the **Chan1-ATRIUM** output terminals. 15.4 Start pacing and measure output voltage during and immediately after stimuli in the phases shown in Figure 5 or Figure 6 below. 15.5 Repeat 1.2-1.4 above for the **Chan2-Vent**.	Phases for PCB's 3.14+ (Fig 5): 1. Ph1: 4.0 to 4.7 V 2. Ph2: > 25 V 3. Ph3: < 0.1 V 4. Ph1. 4.0 to 4.7 V Phases for older PCB's Ver 3.8 to 3.13 (Fig 6): 1: Ph1: 4.0 to 4.7 V 2: Ph2: > 25 V 3: Ph3: 8.0 to 9.2 V 4. Ph4: < 0.1 V	15.4 Chan1-Atrium 1) 2) 3) 4) 15.5 Chan2-Vent 1) 2) 3) 4)	



Phase	Voltage(V)	Duration(ms)
1	4 - 4.7	any
2	25 - 31	2 ± 0.2*
3	0 - 0.1	12 ± 3**

*may be 0.5 to 10 ms if programmed by PC
**if programmed by PC then equals (14-Phase 2)

Figure 5 The correct observed signal from balance charge pacing (BPC-2 for PCB Ver 3.14+, i.3. SGU with Ser.No. > 300, [excl. 1000-1100])



Phase	Voltage	Duration
1	4 - 4.7	any
2	25 - 31	2 ms *
3	8.0 - 9.2	12 ± 1.5 ms
4	0 - 0.1	7.5 ±2.5 ms

Figure 6 The correct observed signal from balance charge pacing (BPC for PCB Ver 3.8 to 3.13, i.e. SGU with Ser.No. <= 300 & 1000-1100)

7. Factory testing

The EPS320 Stimulus Generator Unit (SGU) is calibrated in the factory by the use of certain 0.1% tolerance components and is tested by a computerized Final Acceptance test jig which verifies all published performance specifications using > 150 measurements. Stimulus interval timing accuracy is verified dynamically during operation by mutual verification of the two independent CPU electronic clocks in the PC and the SGU. Table below lists the Final Acceptance Test Items.

EPS320 SGU in-factory Final Acceptance Test Items (and acceptance ranges)	OK
1. Test Ch1 output for delay (± 1 ms or 0.1%), pulse width (± 0.15 ms) and current amplitude (± 2% or ± 0.2 mA) for following settings: a) Ch1,0.5mA,10ms, 1k load; b) Ch1, 5mA, 4ms, 1k load; c) Ch1,21mA,10ms, 1k load; d) Ch1 25mA,10ms,0.5k load;	
2. Test Ch2 output as per Ch1 above.	
3. Calibrate zero and 0.1 mA current (±0.015mA) output for Ch1 and Ch2	
3. Test Sync Output for delay, pulse width and voltage amplitude (+5V CMOS, 50 ms)	
4. Test internal catheter tip ECG sensing amplitude and delays from Ch1 and Ch2 (2mV to 36mV, 4 gains (50x, 200x, 400x and 800x), ±30%, 10kOhm input impedance)	
5. Test external ECG gains (1.0Vpp and 2.0Vpp for FSD, ± 10%)[1]	
6. High Impedance Threshold for Ch1 and Ch2 (2Kohm ±10% at 18mA output)	
7. Time to High Stim Rate Alarm (290ms ±20ms)	
8. Time to SGU Watchdog timer alarm (575ms ±50ms)	
9. SGU pulse width clock accuracy (8.0 MHz ± 0.15MHz or 2%)	
10. Backup Battery charge status	
11. Manual Backup panel buttons	
12. Backup Pacing pulse current amplitude (±2%), pulse width 2ms ± 0.15ms and interval (< or ±1ms)	
13. Emergency Fixed Rate Pacing pulse current amplitude (5.0mA ±0.5mA), pulse width (2.0ms ±0.5ms) and interval (650ms ± 100ms).	
14. Computer Link Port function	
15. Auxiliary Port signals (+5V CMOS)	

[1] For earlier SGU Serial No.'s < 300 and 1000-1100 (PCB Ver < 3.12), FSD is 1.0Vpp and 1.6Vpp ± 10%.

8. EPS320 self testing – for information only

The EPS320 stimulators self-test certain functions, at power On Self Test (POST) and also continuously during operation. Refer to Service Manual for Error codes and messages.

8.1 POST Self Test

EPS320 Stimulator self tests during POST – because SGU unit may be left in of- standby state permanently, POST is performed whenever PC connects to the SGU and if user presses Manual Backup Mode button. All tests of stimulus generation are performed into a 1kOhm test load.
POST Errors are displayed on SGU front panel as:

t,E,S,t, X,X,X
, E,r,r / x,x,x

SGU POST Self Test Component	Under Conditions	Pass Range
1. External power supply voltage	Load 300-400mA	> 12.0V =OK
2. Backup Battery Voltage	Load 300-400mA	> 11.0V = OK 8.5 to 11.0V = Low <= 8.5V = Bat. Error
3. Backup Battery Self Test, under load	Load 68 Ohms	> 8.6V = OK
4. Pulse Generator Self Test, both channels	10mA (2ms pulse width)	8.5mA to 10.5mA = OK
5. Pulse Tolerance Alarm Test, both channels	2mA delivered vs. programmed 5mA / 5ms	Alarm raised = OK
6. High Stim Rate Alarm Test (interval < 300ms)	Pulses 1.2 mA / 4ms at 200ms interval	Alarm raised = OK
7. DC Detect Alarm Test	DC current of 0.96mA into test load for 280ms	Alarm raised = OK
8. Emergency Battery Voltage Self Test	Under load of 1.6mA	> 8.0V = OK

8.2 SGU self monitoring during operation

The EPS320 SGU performs the following monitor functions during operation.

SGU Self Test Component	Alarm Threshold	Alarm
1. External DC power supply OK	>= 12.0V	BATTERY_LOW
2. Backup Battery Low	< 11 V	b,A,t,t ,L,O
2. Pulse Tolerance Alarm	If delivered pulse is >25% out of tolerance for 200 stimuli in any session	,t,o,L ,E,r,r
3. PC CPU clock v.s. SGU Microcontroller Clock timing alarm	If clock discrepancy is > 2.5% for a total of more than 8 seconds	PC displays Flash Message: “Timing Err”.
DC Output Alarm	If DC current on output > 0.64mA, for > 200ms	_,d,c,_ ,E,r,r
High Stim Rate Alarm Test	Pulse > 0.8mA with interval < 300ms without preceding HSRD_Override command	R,A,t,E ,E,r,r
Communication with PC	No communication with PC for 300ms for 3rd time	N,o,P,C ,E,r,r
Comms data integrity	NOISY SGU COMM	r,E,r,r ,E,r,r on SGU