TESTING MEDTRONIC MODEL 5392 PACEMAKER USING FLUKE SigmaPace 1000 EXTERNAL PACEMAKER ANALYZER

Note: Medtronic Inc. is not responsible for the support or updates to the Fluke SigmaPace 1000. Medtronic supports the 5392 and this procedure is written to support Medtronic Customers in the use of testing with the Fluke SigmaPace 1000.

Medtronic does not specifically recommend or promote the use of any one specific transvenous temporary pacemaker analyzer for the purpose of testing Medtronic EPG's.

5392 Service Life

Medtronic will no longer service or calibrate EPGs that are more than 7 years old. EPGs that are equal to or less than 7 years old can be serviced and calibrated.

Medtronic recommends that the 5392 have the calibration verified at minimum once every 12 months. When the 5392 reaches end of Medtronic Service Life, the 5392 can continue to be used, based on the physical condition and continued scheduled preventive maintenance checks (refer to the 5392 Technical Manual). The scheduled preventive maintenance checks would have to be completed using a transvenous temporary pacemaker analyzer. The testing would verify the functions as stated within the 5392 Checkout Manual and the test results to be found within the stated tolerances of 5392 Checkout Manual.

Contact Medtronic Instrument Technical Services, 1 (800) 638-1991 with questions regarding testing and functionality.

Introduction:

The Fluke SigmaPace 1000 is a menu-driven analyzer designed to facilitate testing of external transvenous pacemakers such as the Medtronic Model 5392 Dual Chamber Temporary Pacemaker. Many of the tests are automated to the extent that, once a test is initiated, no operator intervention is required; the analyzer performs those actions required to produce a test result.

The following Medtronic 5392 tests are a compilation of the tests specified in the 5392 Checkout Manual and Technical Manual. Although operation of the tester is quite intuitive, the instructions are provided in a step-by-step format for the benefit of the new user. Instructions in **bold** describe the desired test and/or result; indented instructions in *italics* provide a keystroke-by-keystroke "how-to" guide to each test.

For detailed operation and function of the 5392 refer to the Technical Manual or Checkout Manual. The 5392 can provide additional "Optional Test" that could be performed on the temporary pacer.

1. CHECK BATTERY.

- *Always test a pacemaker using, two "fresh" IEC type LR6-sized (AA-sized) 1.5 V alkaline batteries (Duracell MN1500, Eveready E91 or equivalent).*
- *Turn on the pacemaker and observe completion of the self-test, after which the device default settings will appear.*

Default settings when 5392 is powered "ON" are:

Upper Display Screen: Figure A

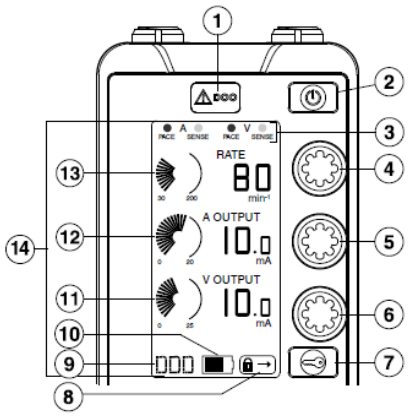
Rate = 80 bpm
A output = 10mA
V Output = 10 mA

Mode: DDD

Lower Display Screen: (Press the  *(Enter key) on 5392 to display), Figure B*

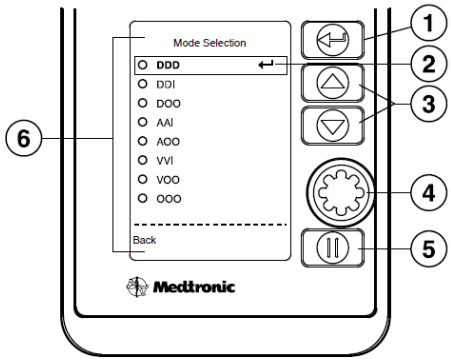
A Sensitivity = 0.5 mV
V Sensitivity = 2.0 mV
A – V Interval = 170 ms
Upper Rate = 110 ppm
PVARP = 300ms
Atrial Tracking = ON
Settings: Automatic

NOTE: *After the power up self-test function is completed a "MODE Selection" screen is displayed, Figure B. This screen can be changed to "Parameters Menu" by pressing*  *, or the screen will revert to "Parameter Menu" after 30 seconds with no User interaction.*
Also, the Lower Display will go blank after 1 minute if there is no User interaction.
See page 9, of these instructions.



1 DOO/Emergency key	8 Lock indicator
2 On/Off key	9 Pacing mode indicator
3 Pacing and sensing status bar indicators	10 Battery indicator
4 RATE dial	11 V (Ventricular) OUTPUT scale
5 A (Atrial) OUTPUT dial	12 A (Atrial) OUTPUT scale
6 V (Ventricular) OUTPUT dial	13 RATE scale
7 Lock/Unlock key	14 Upper screen

Figure A



1 Enter key
2 Selection indicator
3 Up/Down arrow keys
4 Menu Parameter dial
5 Pause key
6 Lower screen

Figure B

Set up for the Sigma 1000 and 5392:

DEMAND MODE: Verify operation as a "demand" pacemaker, i.e. pacing is inhibited in the presence of a "native" ECG signal. Both channels are tested simultaneously.

- *On power-up, the 5392 pacemaker will default to "DDD" pacing mode.*
- *Verify the default setting of the 5392 pacer for a Rate of 80 and both Atrial and Ventricular outputs at 10 mA.*
- *Connect the Fluke SigmaPace 1000 to the 5392 pacer using the leads supplied with the Analyzer, connected to the 5433A and 5433V Patient Cables.*
- *Depress the Yellow "ENT/POWER ON" button on the SIGMAPACE analyzer.*
- *Depress "F2" (INV) to select the "Invasive" category. Figure 1*
- *Depress "F1" (NEXT) to accept a 500 Ohm load for both A and V tests. Figure 2*
- *Depress "F1" (Pulse Output). Figure 3*
- *Depress "F3" (DUAL A & V) to test both channels simultaneously.*
- *Depress "F1" (test will start automatically).*

- *The analyzer will perform a brief calculation, and then it will begin to display the pacer's (5392) RATE along with values for "Amp"(Output), "Rate"(beats per minute), "Width" (Pulse width), "AV Int" (AV Interval), note there is a column for the A (Atrial) and a column for V (Ventricle), channels . Figure 4.*

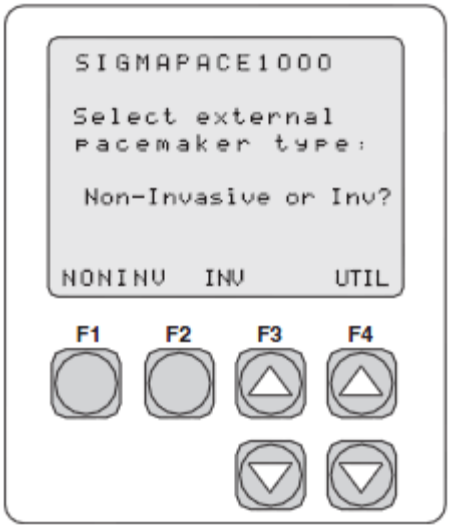


Figure 1

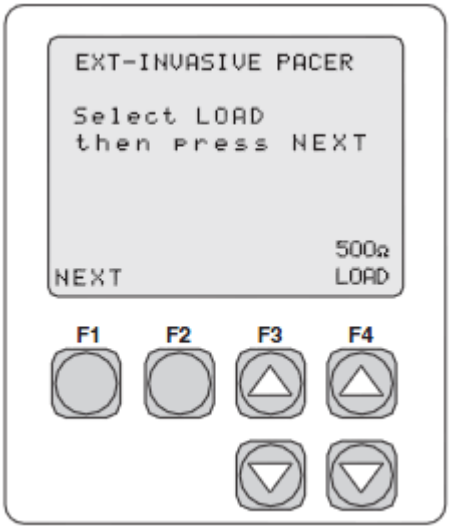


Figure 2

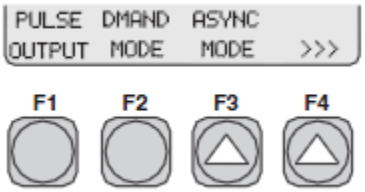


Figure 3

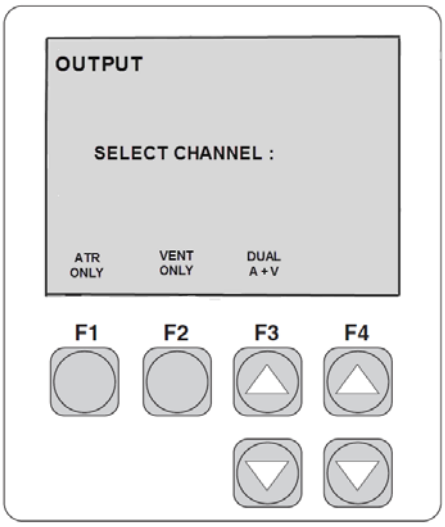


Figure 4

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1. **<u>PULSE OUTPUT TEST:</u>** (Fig 3 – above F1)

Verify Accuracy (and Independence) of RATE (BPM), OUTPUT (mA), Rapid Atrial Pacing (RAP), PULSEWIDTH (ms) and A-V Interval (ms) for both pacemaker channels (Atrial and Ventricular).

- Set 5392 pacer as follows and compare results on SigmaPace 1000 to ranges shown in the table below:

Output (O/P) = mA			Rate = BPM		Pulse Width = ms	
Ch.	Set O/P	(Measured Range)	Set Rate	(Measured Range)	Spec. Pulse Width	(Measured Range)
A	1.0	(0.9 – 1.1)	30	(29 - 31)	1.0	(0.90 - 1.10)
V	1.0	(0.9 – 1.1)	30	(29 - 31)	1.5	(1.35 - 1.65)
A	10	(9.0– 11.0)	80	(78 – 82)	1.0	(0.90 - 1.10)
V	10	(9.0 - 11.0)	80	(78 – 82)	1.5	(1.35 - 1.65)
A	20	(18.0 – 22.0)	120	(117 - 123)	1.0	(0.90 - 1.10)
V	25	(22.5 - 27.5)	120	(117 - 123)	1.5	(1.35 - 1.65)
A	20	(18 – 22)	200	(196 - 204)	1.0	(0.90 - 1.10)
V	25	(22.5 - 27.5)	200	(196 - 204)	1.5	(1.35 - 1.65)
Tolerance = +/- 10%			Tolerance = +/- 2 %		Tolerance = +/- 10%	

***Complete the A-V Interval test from the "Pulse Output" Test Screen on the Sigma Pace 1000. Use test points and tolerances below, for the A-V Interval test.*

2. A-V INTERVAL Test:

Rate	A-V Interval
30	250 ms (237.5 – 262.5 ms)
80	170 ms (161.5 – 178.5 ms)
120	100 ms (95 – 105 ms)
200	50 ms (47.5 – 52.5 ms)

Tolerance = +/- 5%

Note: The A/V interval will be measured in the PULSE OUTPUT screen, (see Figure 4) of the SigmaPace 1000 and can be verified while doing the Rate, Output and Pulse Width Testing.

3. EMERGENCY DOO Test: (Optional)

Complete the Emergency DOO test from the "Pulse Output" Test Screen on the Sigma Pace 1000, Per Figure 4 above. Use test points and tolerances below, for the Emergency DOO test.

Press the *DOO* key on the front panel of the 5392, refer to Figure A, to initiate or start Emergency Pacing. The 5392 will continue to pace at the programmed rate, while the atrial Output will increase to 20 MA and the Ventricular Output will increase to 25 mA.

	Test Points	Threshold	Tolerance
Rate:	**200 bpm**	**(196 – 204 bpm)**	**± 2%**
A - Output	**20 mA**	**(18.0 – 22.0 mA)**	**± 10%**
V – Output	**25 mA**	**(22.5 - 27.5 mA)**	**± 10%**

4. RAPID ATRIAL PACING Test:

**Complete Rapid Atrial Pacing (RAP) test from the "Pulse Output" test screen on the SigmaPace 1000. The test for RAP can be completed in the PULSE OUTPUT test window by just using RAP on the 5392 and viewing that measurement on the display screen of the SigmaPace 1000.

Verify that only the Atrial channel pulses at the set rate and amplitude.

- *On 5392 pacer, press Menu key*  *and then press the down arrow*  *to access Rapid Atrial Pacing on the 5392. Then press*  , again to adjust the R.A.P. rate.
- *Using the control knob, adjust the R.A.P. rate and press and hold*  *to initiate Rapid Atrial Pacing.*
- *Example: Adjust "RAP" to 180 bpm, then depress and hold the*  *on the 5392 keypad.*

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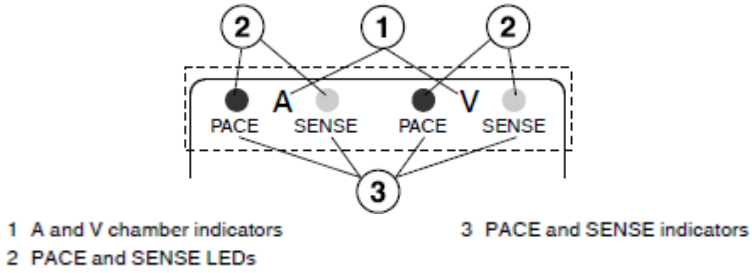
- *From the SigmaPace 1000 "PULSE OUTPUT" test Screen, the "A" channel should display a rate between 176 and 184 BPM. The "V" channel will be blank on the SigmaPace 1000 display screen.*

The A Pace LED will flash at the RAP rate. The V Pace LED will stop flashing, indicating no V Pace or output.

Verify on the Analyzer that the Rapid Atrial Rate below is within the prescribed tolerances and R.A.P. ranges.

R.A.P. Setting	Specified Tolerance	R.A.P. Range
180 ppm	+/- 2%	176 – 184 ppm
250 ppm	+/- 2%	245 – 255 ppm
360 ppm	+/- 2%	353 – 367 ppm
800 ppm	+/- 2%	784 – 816 ppm

Note: The indicators are the Pace and Sense L.E.D.'s under the V of the 5392, below.



5. SENSITIVITY TEST:

With pacer set in "DEMAND" mode, (definition on page 18), each channel is independently tested to verify the accuracy of the "SENSITIVITY" controls. 5392 SENSITIVITY is tested using an "upright" ("+R", i.e. positive polarity) test waveform, then testing is repeated using an "inverted" ("- R", i.e. negative polarity) test waveform. Power on the 5392 pacer and verify default settings of a rate of 80 bpm and set both outputs (A output and V output) to 10 mA.

5392 Atrial Sensitivity Test

Test Points	Threshold	Tolerance
1.0 mV	**(0.40 mV – 1.6 mV)**	**+/- 60%**
5.0 mV	**(3.0 mV – 7.0 mV)**	**+/- 40%**
10.0 mV	**(6.0 mV – 14.0mV)**	**+/- 40%**

- *On the 5392 pacer, set the Ventricular output to zero "0" and set the Atrial output to 10 mA.*

  Press the  *to access "A SENSITIVITY", and then set values according to the following table, above. Verify that the analyzer results fall within the given threshold ranges.*

Fluke SigmaPace 1000 Analyzer Function:

- *On the SigmaPace, depress "ESC" twice.*
- *Depress "F4" to access more test menu options.*
- *Depress "F2" (SENSE AMP).*
- *Depress "F1" (ATR). Figure 5*
- *Depress "F1" (NEXT) to accept a 500 Ohm load. Figure 6*
- *Depress the Down Arrow key under "F4" to change 30ms to 20 ms. Then press "F1" (NEXT) to accept a 20ms SSQ wave (Sine Square Wave) for ATR. Figure 7*
- *Depress and hold the Down Arrow key under "F4" until the mV value is ".05". Figure 8*
- *Depress "F1" (START). Analyzer will incrementally increase the pulse train amplitude of ECG signal to the Atrial channel until pacing is inhibited. (Sense L.E.D illuminates.) The value displayed should fall between the ranges displayed above. Figure 9.*
- *On the 5392 EPG increase the "A" Sensitivity to the next test point value.*
- *Depress the SigmaPace "F1" (RESTART) key; the test will pick up at the last value.*
- *Repeat this process as required with any remaining test points.*

Optional:

- *To test with reverse polarity, depress "FI" (RESTART). Figure 5*
- *Depress "F3" (POL). (As shown in Figure 8, below.)*

5392 Ventricular Sensitivity Test:

Test Points	Threshold	Tolerance
1.0 mV	**(0.45 mV – 1.55 mV)**	**+/- 55%**
3.0 mV	**(1.35 mV – 4.65 mV)**	**+/- 55%**
10 mV	**(4.5 mV – 15.50 mV)**	**+/- 55%**
20 mV	**(9.0 mV – 31.0 mV)**	**+/- 55%**

- On the 5392 pacer, set the Atrial output to zero "0" and set the Ventricular output to 10 mA.

  Press the  to access "V SENSITIVITY", and then set values according to the following table, . Verify that the analyzer results fall within the given ranges.

Fluke SigmaPace 1000 Analyzer Function:

- *Press the "ESC" until you are at the Menu screen.*

- *Depress "F4" to access more test options, if needed.*
- *Select (SENSE AMP).*
- *Depress "F2" (VENT). Figure 5*
- *Depress "F1" (NEXT) to accept a 500 Ohm load. Figure 6*
- *Depress "F1" (NEXT) to accept a 40.0 ms SSQ wave for VENT. Figure 7*
- *Depress and hold the SIGMAPACE 1000 Down Arrow key under "F4" until the mV value is ".05". Figure 8*
- *Depress "F1" (START). Analyzer will increment amplitude of ECG pulse train amplitude to Vent. channel until pacing is inhibited. The value displayed should fall between the ranges for threshold displayed above. Figure 9.*
- *On the 5392 EPG increase the "V" Sensitivity to the next test point value.*
- *Depress the SIGMAPACE "F1" (RESTART) key.*
- *Depress the SIGMAPACE "F1" (START) key; the test will pick up at the last value.*
- *Repeat this process as required with any remaining test points.*

Optional:

- *To test with reverse polarity, depress "FI" (RESTART). Figure 9*
- *Depress "F3" (POL). (As shown in Figure 8, below.)*

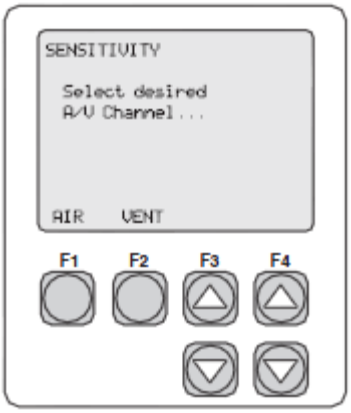


Figure 5

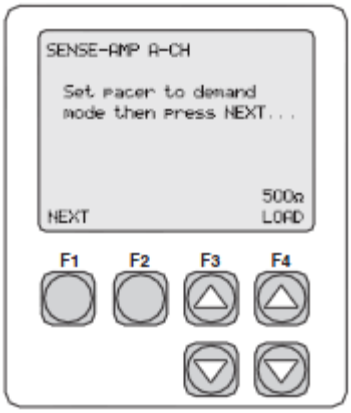


Figure 6

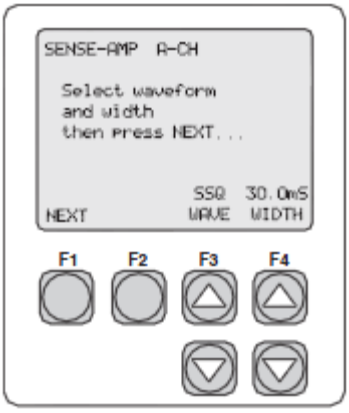


Figure 7

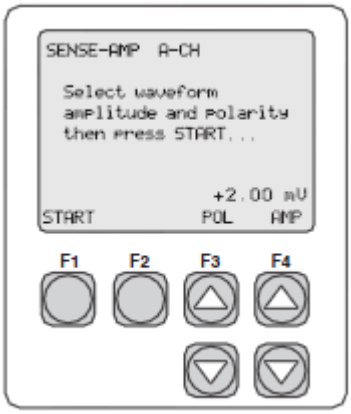


Figure 8

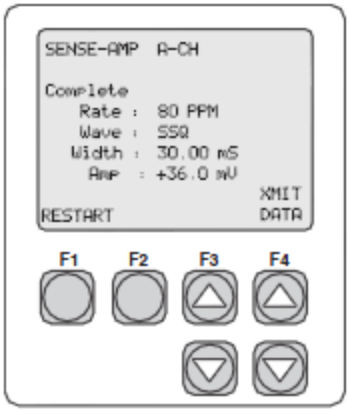
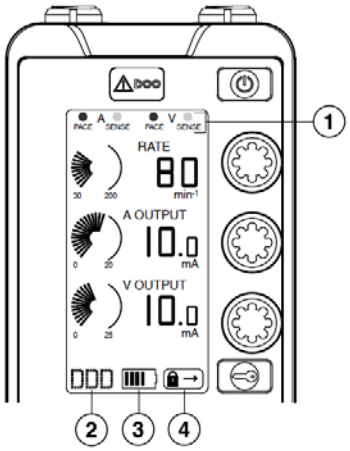


Figure 9

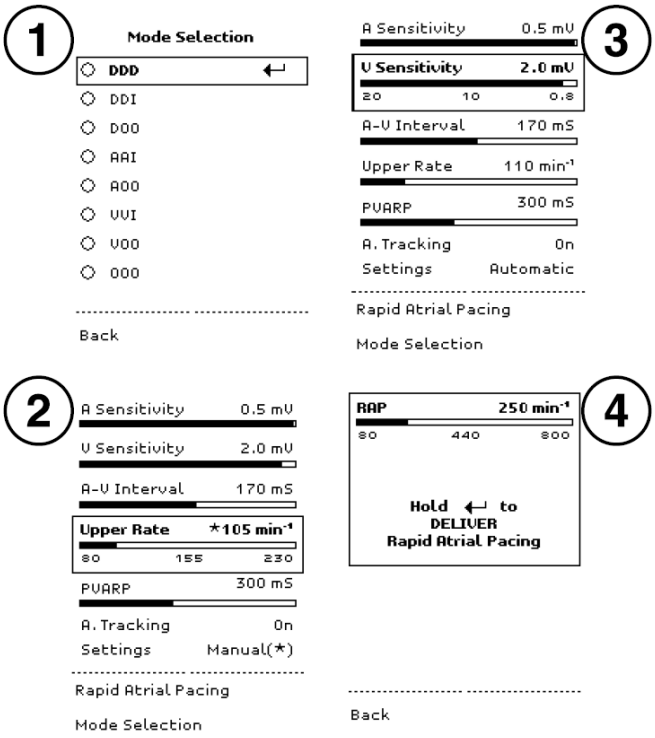
5392 Front Display Controls - Indicators - Features

Upper Screen Display



1 Pacing and sensing status bar indicators
2 Pacing mode indicator
3 Battery status indicator
4 Lock indicator

Lower Screen Menu's



** Screen #1 will revert to screen #2 after 30 seconds post power up.
** Screen #2 - #3 - #4 will go blank after 1 minute if there is no User interaction with the 5392.

5392 Device Specifications

Pacing modes	DDD, DDI, DOO, AAI, AOO, VVI, VOO		
RATE	Range (in min^{-1})	Increments (in min^{-1})	Tolerance
	30 – 50 50 – 100 100 – 170 170 – 200	5 2 5 6	30 – 200 ±2%
RAP rate	Range (in min^{-1})	Increments (in min^{-1})	Tolerance
	80 – 180 180 – 250 250 – 360 360 – 800	20 5 10 20	80 – 360 ±2% 380 – 800 ±4%
Output amplitude			
Atrial	Range (in mA)	Increments (in mA)	Tolerance
	0.1 – 0.4 0.4 – 1.0 1.0 – 5.0 5.0 – 20	0.1 0.2 0.5 1.0	0.1 – 20 Greater of ±0.1 mA or ±10% (200-1000 Ω)
Ventricular	Range (in mA)	Increments (in mA)	Tolerance
	0.1 – 0.4 0.4 – 1.0 1.0 – 5.0 5.0 – 25	0.1 0.2 0.5 1.0	0.1 – 20 Greater of ±0.1 mA or ±10% (200-1000 Ω) 20 – 25 ±10% (200–500 Ω)
Pulse width (fixed)			
Atrial	1.0 ms ±10%		
Ventricular	1.5 ms ±10%		
Sensitivity[a]			
Atrial	Range (in mV)	Increments (in mV)	Tolerance
	0.4 – 0.8 0.8 – 2.0 2.0 – 3.0 3.0 – 10	0.1 0.2 0.5 1.0	< 0.8 mV ±60% ≥ 0.8 mV ±40%

Ventricular	Range (in mV)	Increments (in mV)	Tolerance
	0.8 – 1.0 1.0 – 3.0 3.0 – 10 10 – 20	0.2 0.5 1.0 2.0	±55%
A-V Interval			
	Paced A-V (PAV)	Sensed A-V (SAV)	
Formula	300 – (1.67 x RATE in min^{-1}) within range	= PAV – 30 within range in DDD pacing mode = PAV within range in DDI pacing mode	
Range (in ms)	50 – 250 – Auto 20 – 300 – Manual	50 – 250	
Increments (in ms)	10	10	
Tolerance	Greater of ±5 ms or ±5%	Greater of ±15 ms or ±15%	
Refractory period			
Atrial			
At atrial event	SAV or PAV, whichever is in effect		
	310 ms +5/-30 ms or 75% of the base rate, whichever is lower (AAI pacing mode only)		
At ventricular event (PVARP)	Auto (all values are +5/-30 ms)	Rate range (in min^{-1})	PVARP (in ms)
		≤ 100 > 100 and ≤ 150 > 150 and ≤ 180 > 180	300 250 230 200
	Manual (all values are +5/-30 ms)	Range (in ms)	Increments (in ms)
		150 – 500	10
Upper Rate			
Auto	RATE + 30 min^{-1} ±10%	Minimum of 110 min^{-1}	
Manual	Range (in min^{-1})	Increments (in min^{-1})	Tolerance
	80 – 100 100 – 170 170 – 200 200 – 214 214 – 230	2 5 6 7 8	±10%

Safety pace	RATE < 86 min^{-1}	Occurs 110 ms after atrial pace, if A-V interval is set to more than 110 ms, or at programmed A-V interval if A-V interval is set to less than 110 ms
	RATE ≥ 86 min^{-1}	Occurs 70 ms after atrial pace, if A-V interval is set to more than 70 ms, or at programmed A-V interval if A-V interval is set to less than 70 ms
Mode switch detection rate	= 171 min^{-1}, if the Upper Rate is < 165 min^{-1} = Upper Rate + 10 min^{-1}, if the Upper Rate is ≥ 165 min^{-1}	
Blanking[b]		
Atrial		
200 ms +5/-30 ms – after atrial pace		
100 ms +2/-30 ms – after atrial sense		
100 ms +2/-15 ms – after ventricular pace/sense		
Ventricular		
30 ms +2/-15 ms – after atrial pace		
200 ms +5/-30 ms – after ventricular pace		
120 ms +2/-30 ms – after ventricular sense		
RATE limit (non-RAP)	230 min^{-1}	If a non-RAP rate exceeds 230 min^{-1}, pacing is terminated. A recoverable error message is displayed in the lower screen.
Nominal values - DDD pacing mode		**Nominal values - DOO for Emergency**
Pacing mode	DDD	DOO for Emergency
RATE	80 min^{-1}	When the DOO/Emergency key is pressed, current setting (or 80 min^{-1} if the temporary pacemaker was off before the DOO/Emergency key was pressed).
Output amplitude		
Atrial	10 mA	20 mA for Emergency
Ventricular	10 mA	25 mA for Emergency
Pulse width (fixed)		
Atrial	1.0 ms	
Ventricular	1.5 ms	
Sensitivity		
Atrial	0.5 mV	Asynchronous for Emergency
Ventricular	2.0 mV	Asynchronous for Emergency

AV Interval		
Sensed	140 ms	
Paced	170 ms	When the DOO/Emergency key is pressed, current manual setting (or 170 ms if temporary pacemaker is off, or automatic rate-dependent when the temporary pacemaker is on)
PVARP	300 ms	Not applicable
Upper Rate	110 min^{-1}	Not applicable
RAP rate	250 min^{-1}	
Dimensions		
Height	20.3 cm ±15%	
Width	8.6 cm ±15%	
Depth (without dials)	4.45 cm ±15%	
Weight (with battery)	680 g maximum	
Temperature		
Operating	15 °C to 35 °C[c]	
Storage (without battery)	-40 °C to 70 °C	
Humidity (storage)	> 80% and ≤ 95% at 35 °C, use after 48 hours dry time ≥ 10% and ≤ 80% at 35 °C, for immediate use	
Battery type	Two IEC type LR6-sized (AA-sized) 1.5 V alkaline batteries (Duracell MN1500, Eveready E91 or equivalent)	
Battery life	7 days minimum, when the RATE is 80 min^{-1}, and all other parameters are at the nominal values. Higher amplitudes and rates decrease battery life.	
Operation after battery removal	30 s (typical) under the following conditions: RATE of 80 min^{-1} or less, A OUTPUT and V OUTPUT of 10 mA or less, backlight off, and lower screen blank.[d]	

[a] When sensing 40 ms-wide Haversine waveform for ventricular inputs, 20 ms-wide Haversine waveform for atrial inputs.
[b] When tested with a 1 ms square pulse with sufficient amplitude.
[c] Within the ranges of 10 °C to 15 °C and 35 °C to 43 °C, the specification for OUTPUT is derated an additional ± 5%, the specification for SENSITIVITY is derated an additional ± 7%; and the specification for RATE is not derated.
[d] Medtronic does not recommend replacing the batteries while the pacemaker is turned on or actively pacing the patient.

Pacing information tables

Pacing mode	AOO	VOO	AAI	VVI
A (Atrial) and V (Ventricle) Indicators	**A**	**V**	**A**	**V**
PACE and SENSE Indicators	PACE	PACE	PACE + SENSE	PACE + SENSE
Instructions				
1. Set OUTPUT				
A OUTPUT	On	Off	On	Off
V OUTPUT	Off	On	Off	On
2. Set Sensitivity				
A Sensitivity	ASYNC	NA	On	NA
V Sensitivity	NA	ASYNC	NA	On
3. Set **A Tracking**	NA	NA	NA	NA

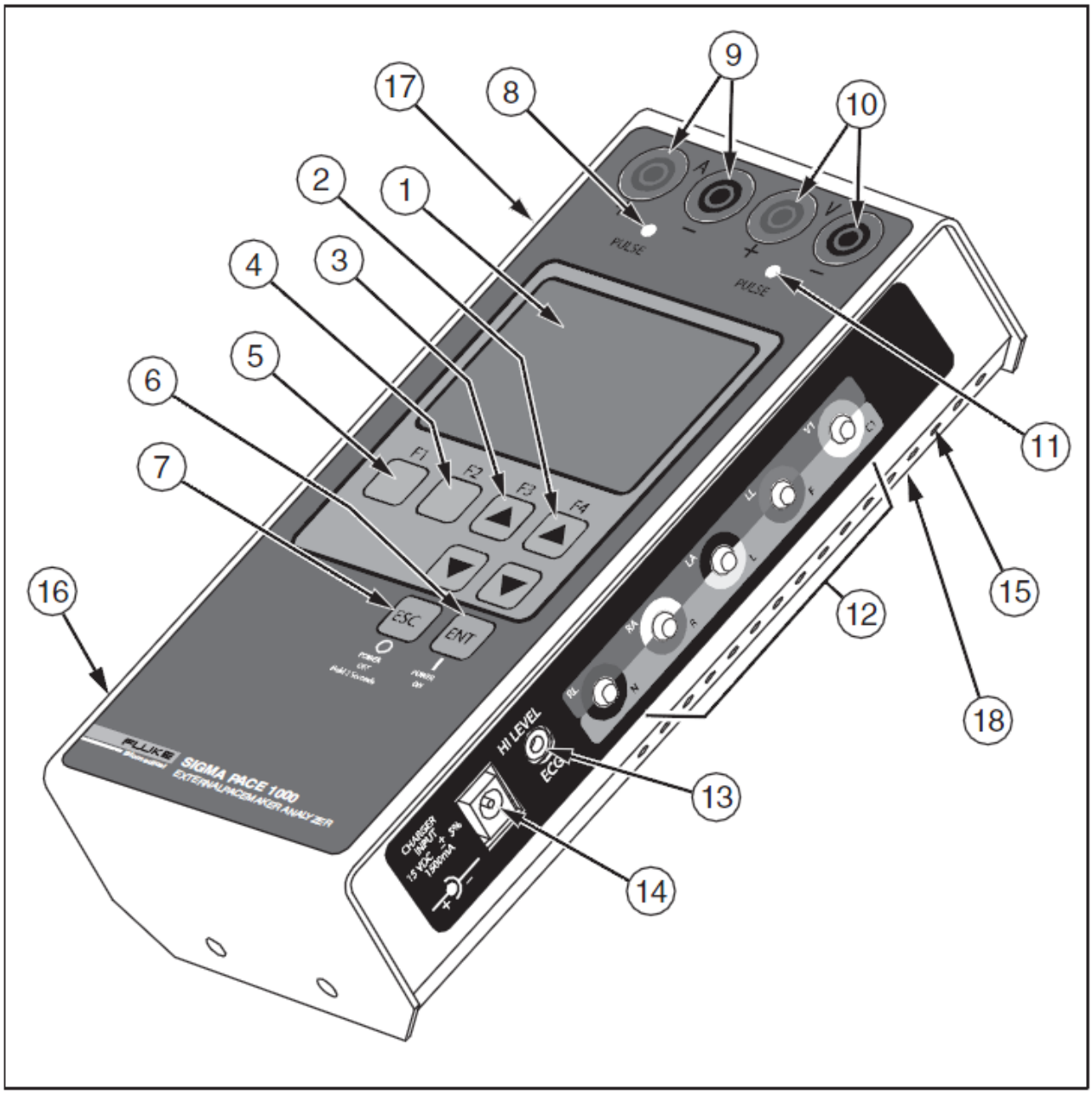
Table 5. Temporary pacemaker dual chamber pacing setup table

Pacing mode	DOO	DDD	DDI
A (Atrial) and V (Ventricle) Indicators	**A+V**	**A+V**	**A+V**
PACE and SENSE Indicators	PACE (A) + PACE (V)	PACE + SENSE (A) and PACE + SENSE (V)	PACE + SENSE (A) and PACE + SENSE (V)
Instructions			
1. Set OUTPUT			
A OUTPUT	On	On	On
V OUTPUT	On	On	On
2. Set Sensitivity			
A Sensitivity	ASYNC	On	On
V Sensitivity	ASYNC	On	On
3. Set **A Tracking**	NA	On	Off

Table 6. Rate and interval conversion chart for RATE and RAP

Rate		RAP	
Rate	Interval	Rate	Interval
30 min^{-1}	2000 ms	80 min^{-1}	750 ms
35 min^{-1}	1714 ms	100 min^{-1}	600 ms

Fluke SigmaPace 1000 Features and Controls



Number	Description
Top Panel	
1	LCD Readout (8 Lines X 21 Characters)
2	F4 / UP and DOWN Arrow Keys
3	F3 / UP and DOWN Arrow Keys
4	F2 Key
5	F1 Key
6	ENTER and POWER ON Key
7	ESCAPE and POWER OFF Key
8	Atrial Channel Sense Indicator (Yellow LED)
9	Atrial Channel Pacemaker Input Jacks (4 mm) Red: Positive Black: Negative
10	Ventricular Channel Pacemaker Input Jacks (4 mm) Red: Positive Black: Negative (Transvenous and Transcutaneous)
Right Side Panel	
11	Ventricular Channel Sense Indicator (Yellow LED)
12	Low Level ECG Output (Disposable Snap Compatible)
13	High Level ECG Output (Subminiature Phone Jack)
14	Charger / dc Power Supply Input Jack
15	Ventilation Slots
Left Side Panel	
16	Load Current (Phantom Battery) Input Connector
17	RS-232 Serial Port
Bottom Panel	
18	RESET Button

Definitions

Demand Mode

This qualitative test verifies the demand mode pacemaker's ability to interact with a simulated ECG signal. The Analyzer first measures the pacemaker's applied pulse rate then computes "underdrive" and "overdrive" rates for the simulated ECG signal. Initially, the underdrive rate is 90 % of the applied pacemaker rate and the overdrive rate is 110 % of the applied pacemaker rate.

When testing the pacemaker, operating in the demand mode, output should be active (ON) with the underdrive ECG signal and then inhibited (OFF) when the overdrive ECG signal is selected. The rates of these underdrive and overdrive ECG signals can be adjusted across a wide physiological range using the Analyzer top panel controls.

Asynchronous Mode

This qualitative test verifies the continuous (or non-demand) mode pacemaker's ability to interact with a simulated ECG signal. The Analyzer first measures the pacemaker's applied pulse rate then computes underdrive and overdrive rates for the simulated ECG signal. Initially, the underdrive rate is 90 % of the applied pacemaker rate and the overdrive rate is 110 % of the applied pacemaker rate.

When testing the attached pacemaker, operating in the continuous (or non-demand) mode, output should be active (ON) when either the underdrive ECG signal or overdrive ECG signal is selected. The rates of these underdrive and overdrive ECG signals can be adjusted across a wide physiological range by the user.

Amplitude Sensitivity

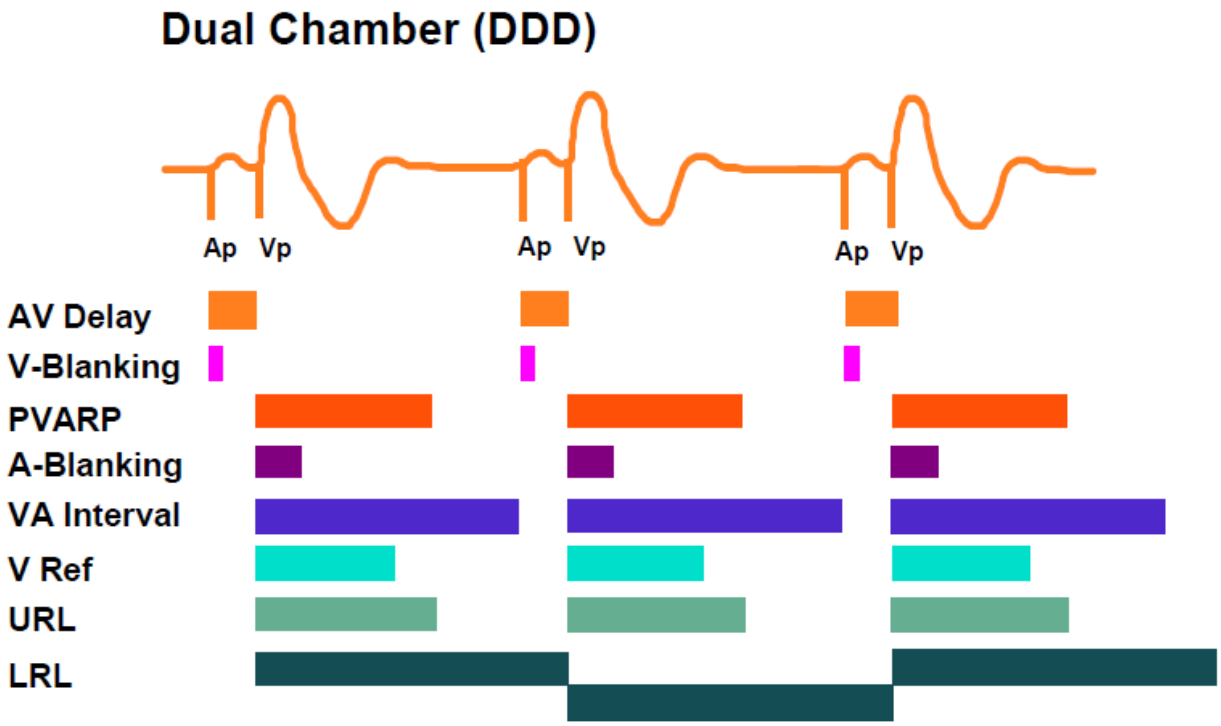
This quantitative test determines the amplitude of the simulated ECG signal required by the demand mode pacemaker. The amplitude of the simulated ECG signal is increased in very small steps until the pacemaker senses it and inhibits the output pulse.

Line Frequency / Noise Immunity

This qualitative test verifies the pacemaker's ability to filter line frequency noise at either 50 or 60 Hz and sense a simultaneously applied simulated ECG signal. The user can change the amplitude of the line frequency noise, while the simulated ECG signal amplitude is fixed.

PVARP – Post Ventricular Atrial Refractory Period

Refractory Period:
In pacing, a programmable parameter that controls the length of time following a paced or sensed beat, during which the pacemaker's sensing circuit does not respond to sensed events.
•PVARP=Post Ventricular Atrial Refractory Period=atrial refractory period
•VRP=Ventricular Refractory Period



During refractory periods, the pacemaker "sees" but is unresponsive to any signals. This is designed to avoid restarting the lower rate interval in the event of oversensing. T-wave oversensing in VVI and AAI modes will occur if refractory periods are too short. In the AAI mode, the pacemaker may even sense the QRS complex ("far-field R wave") if the refractory period is not long enough.

Events that fall into the refractory period are sensed by the pacemaker (the marker channel will display a "SR" denoting ventricular refractory or atrial refractory in single chamber systems) but the timing interval will remain unaffected by the sensed event.

A refractory period is started by a paced, non-refractory, or refractory sensed event.

Refractory Period:

In pacing, a programmable parameter that controls the length of time following a paced or sensed beat, during which the pacemaker's sensing circuit does not respond to sensed events.

VRP = Ventricular **R**efractory **P**eriod

Refractory Period

These two related qualitative tests determine the demand mode pacemaker's ability to sense ECG activity immediately following either a paced event (PRP) or sensed ECG event (SRP).

Paced Refractory Period (PRP)

The Analyzer first measures the pacemaker's applied pulse rate, and then generates a simulated ECG signal within the expected PRP interval. See Figure 3-2. This coupling interval is slowly extended until the simulated ECG signal falls outside the PRP. The signal is then sensed by the pacemaker, causing the escape interval to reset. The result is a longer pacing pulse interval.

Sensed Refractory Period (SRP)

The Analyzer then generates a second simulated ECG signal immediately trailing the first simulated ECG signal used to determine the PRP. See Figure 3-3. This coupling interval is slowly extended until the simulated ECG signal falls outside the PRP. The signal is then sensed by the pacemaker, causing the escape interval to reset. The result is a longer pacing pulse interval.