

# Application Notes

## SigmaPace™ 1000: Medtronic Temporary External Pacemaker Model 5388 Checkout Procedure

### 1. PRELIMINARY SET UP

- a. Connect the pacemaker output to the analyzer's ATRIAL and VENTRICULAR 4 mm interface jacks using the supplied (red and black) test leads.
- b. Turn on power on both the pacemaker and the analyzer.

*From the main (power-up) menu on the analyzer:*

Press F2: INVasive pacemakers

Press F1: NEXT (Tests pacemaker using the default 500 Ω test load.)

Remaining menu navigation directions are given from this Ext-Invasive Pacer SELECT TEST screen.

**Note:**

Use the F1: HOLD/RELEASE key feature to freeze test results on the analyzer's screen.

Use the analyzer's ESCape key to EXIT out of specific test modes.

### 2. RATE TEST

- a. ARTRIAL RATE  
 (Use SigmaPace 1000 F1: PULSE OUTPUT, F3: DUAL A+V Screen)  
 Operational Mode: AAI  
 Atrial Channel: ON and Ventricular Channel: OFF by pressing the key button on the 5388 and setting the V output to zero.  
 Atrial Channel Output @ 10 mA  
 Press the key button on the 5388 and check the rate settings.

Rate Setting	Specified Tolerance (PPM)	Specified Tolerance (mS)	SigmaPace 1000 Reading	Status Pass / Fail?
30 PPM	± 5 % (28.5 – 31.5)	1900 – 2100	PPM	
80 PPM	± 5 % (76 – 84)	712 – 788	PPM	
120 PPM	± 5 % (114 – 126)	475 – 525	PPM	
200 PPM	± 5 % (190 – 210)	285 – 315	PPM	

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**b. VENTRICULAR RATE**

(Use SigmaPace 1000 F1: PULSE OUTPUT, F3: DUAL A+V Screen)

Operational Mode: VVI

Atrial Channel: OFF by pressing the key button on the 5388 and setting the A output to zero. and Ventricular Channel: ON

Ventricular Channel Output @ 10 mA

Press the key button on the 5388 and check the rate settings.

Rate Setting	Specified Tolerance (PPM)	Specified Tolerance (mS)	SigmaPace 1000 Reading	Status Pass / Fail?
30 PPM	± 5 % (28.5 – 31.5)	1900 – 2100	PPM	
80 PPM	± 5 % (76 – 84)	712 – 788	PPM	
120 PPM	± 5 % (114 – 126)	475 – 525	PPM	
200 PPM	± 5 % (190 – 210)	285 – 315	PPM	

**c. RAPID ATRIAL RATE (RAP)**

(Use SigmaPace 1000 F1: PULSE OUTPUT, F3: DUAL A+V Screen)

Operational Mode: AOO (Access RAP feature via the Medtronic 5388 Menu #3).

Atrial Channel: ON and Ventricular Channel: OFF

Atrial Channel Output @ 10 mA

Rate Setting	Specified Tolerance (PPM)	Specified Tolerance (mS)	SigmaPace 1000 Reading	Status Pass / Fail?
350 PPM	± 5 % (285 – 367.5)	163 – 180	PPM	

**3. PULSE WIDTH**

**a. ATRIAL PULSE WIDTH**

(Use SigmaPace 1000 F1: PULSE OUTPUT, F3: DUAL A+V Screen)

Operational Mode: AAI

Atrial Channel: ON and Ventricular Channel: OFF

Atrial Channel Output @ 10 mA

Rate Setting	Pulse Width	Specified Tolerance (mS)	SigmaPace 1000 Reading	Status Pass / Fail?
80 PPM	1.0 mS	± 5 % (0.95 – 1.05)	mS	

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**b. VENTRICULAR PULSE WIDTH**

(Use SigmaPace 1000 F1: PULSE OUTPUT, F3: DUAL A+V Screen)

Operational Mode: VVI

Atrial Channel: OFF and Ventricular Channel: ON

Ventricular Channel Output @ 10 mA

Rate Setting	Pulse Width	Specified Tolerance (mS)	SigmaPace 1000 Reading	Status Pass / Fail?
80 PPM	1.5 mS	± 5 % (1.425 – 1.575)	mS	

**4. AV INTERVAL**

(Use SigmaPace 1000 F1: PULSE OUTPUT, F3: DUAL A+V Screen)

Operational Mode: DDD (Access this feature via the Medtronic 5388 Menu #1 or use it's power up default output settings.)

Atrial Channel: ON and Ventricular Channel: ON

Atrial Channel Output @ 10 mA

Ventricular Channel Output @ 10 mA

Rate Setting	AV Interval Setting	Specified Tolerance (mS)	SigmaPace 1000 Reading	Status Pass / Fail?
80 PPM	20 mS	± 5 mS (15 – 25)	mS	
80 PPM	150 mS	± 5 % (142 – 158)	mS	
80 PPM	300 mS*	± 5 % (285 – 315)	mS	

\*To set the Medtronic 5388 AV interval @ 300 mS, first decrease the PVARP to minimum (150 mS) on MENU #2 and then go to Menu #1 to access the AV interval function.

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## 5. OUTPUT

### a. VENTRICULAR CHANNEL

(Use SigmaPace 1000 F1:PULSE OUTPUT, F2: VENT ONLY Screen)

Operational Mode: VVI

Rate @ 80 PPM

Atrial Channel: OFF and Ventricular Channel: ON

Ventricular Channel @ 10 mA

Output Setting	Specified Tolerance (mA)	SigmaPace 1000 Reading	Status Pass / Fail?
0.2 mA	± 0.1 mA (0.1 – 0.3)	mA	
5.0 mA	± 10 % (4.5 – 5.5)	mA	
25.0 mA	± 10 % (22.5 – 27.5)	mA	

### b. ATRIAL CHANNEL

(Use SigmaPace 1000 F1: PULSE OUTPUT, F1: ATR ONLY Screen)

Operational Mode: AAI

Rate @ 80 PPM

Atrial Channel: ON and Ventricular Channel: OFF

Atrial Channel @ 10 mA

Output Setting	Specified Tolerance (mA)	SigmaPace 1000 Reading	Status Pass / Fail?
0.2 mA	± 0.1 mA (0.1 – 0.3)	mA	
5.0 mA	± 10 % (4.5 – 5.5)	mA	
20.0 mA	± 10 % (18.0 – 22.0)	mA	

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## 6. EMERGENCY OPERATION MODE

(Use SigmaPace 1000 F1: PULSE OUTPUT, F3: DUAL A+V Screen)

Press pacemaker's top panel key "EMERGENCY" to begin test.

Operational Mode: DDD + EMERGENCY = DOO (Asynchronous Dual Channel)

Rate @ 80 PPM

Atrial Channel: ON and Ventricular Channel: ON

Atrial Channel @ 10 mA (Initial Setting) to 20 mA with EMERGENCY pushbutton depressed

Ventricular Channel @ 10 mA (Initial Setting) to 25 mA with EMERGENCY pushbutton depressed.

Output Setting	Specified Tolerance (mA)	SigmaPace 1000 Reading	Status Pass / Fail?
ATRIAL @ 20 mA	± 10 % (18 – 22)	mA	
VENT @ 25 mA	± 10 % (22.5 – 27.5)	mA	

Return to Synchronous Pacing by pressing the pacemaker's "ON" power key.

## 7. DIRECT CURRENT LEAKAGE

### a. STATIC TESTS (PACEMAKER POWER OFF)

(Use SigmaPace 1000 F4: >>> [Press 2X], F1: DC LEAK, F1 OFF (Static), F1: ATRIAL Screen or F2: VENTricular Screen)

TURN PACEMAKER POWER OFF

Operational Mode: N/A

Atrial Channel: N/A

Ventricular Channel: N/A

Tested Pacemaker Leads	Specified MAXIMUM Tolerance (µA)	SigmaPace 1000 Reading	Status Pass / Fail?
A+ to A-	10.0	µA	
V+ to V-	10.0	µA	

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- b. DYNAMIC TEST-A CHANNEL (PACEMAKER POWER ON)  
 (Use SigmaPace 1000 F4: >>> [Press 2X], F1: DC LEAK, F2: ON (Dynamic), F1: ATRIAL Screen), F1: NEXT

TURN PACEMAKER POWER ON

Operational Mode: AAI  
 Rate @ 80 PPM  
 Atrial Channel: ON and Ventricular Channel: OFF  
 Atrial Channel @ 10 mA

Tested Pacemaker Leads	Specified MAXIMUM Tolerance (µA)	SigmaPace 1000 Reading	Status Pass / Fail?
A+ to A-	10.0	µA	

- c. DYNAMIC TEST-V CHANNEL (PACEMAKER POWER ON)  
 (Use SigmaPace 1000 F4: >>> [Press 2X], F1: DC LEAK, F2: ON (Dynamic), F2: VENTricular Screen), F1: NEXT

TURN PACEMAKER POWER ON

Operational Mode: VVI  
 Rate @ 80 PPM  
 Atrial Channel: OFF and Ventricular Channel: ON  
 Ventricular Channel @ 10 mA

Tested Pacemaker Leads	Specified MAXIMUM Tolerance (µA)	SigmaPace 1000 Reading	Status Pass / Fail?
V+ to V-	10.0	µA	

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- d. DYNAMIC TEST-A+V CHANNELS (PACEMAKER POWER ON)  
 (Use SigmaPace 1000 F4: >>> [Press 2X], F1: DC LEAK, F2: ON (Dynamic), F3: A+V Screen), F1: NEXT

TURN PACEMAKER POWER ON

Operational Mode: DDD

Rate @ 80 PPM

Atrial Channel: ON and Ventricular Channel: ON

Atrial Channel @ 10 mA

Ventricular Channel @ 10 mA

(Third Test Load @ 500 Ω across A+ to V+ terminals)

Tested Pacemaker Leads	Specified MAXIMUM Tolerance (μA)	SigmaPace 1000 Reading	Status Pass / Fail?
A+ to V+	10.0	μA	

## 8. SENSITIVITY

- a. ATRIAL CHANNEL

(Use SigmaPace 1000 F4: >>>, F2: SENSE AMP, F1: ATRial, F1: NEXT, F1: NEXT (DEFAULT SETTING: SSQ WAVE @ 30.0 mS WIDTH), F1: START (+ POLarity and 2.00 mV AMPlitude)

Set pacemaker sensitivity as indicated below for each test.)

Analyzer auto-advances

Operational Mode: AAI (Access this feature via the Medtronic 5388 Menu #1 or simply turn off the VENTRICULAR CHANNEL.)

Waveform: SSQ @ 30 mS

Rate @ 80 PPM

Atrial Channel: ON and Ventricular Channel: OFF

Atrial Channel Output @ 10 mA

Sensitivity Setting	Specified Tolerance and Range (mV)	SigmaPace 1000 Reading	Status Pass / Fail?
0.4 mV*	± 0.25 mV (0.15 – 0.65)	mV	
1.6 mV	± 25 % (1.2 – 2.0)	mV	
3.0 mV	± 25 % (2.25 – 3.75)	mV	
5.0 mV	± 25 % (3.75 – 6.25)	mV	
10.0 mV	± 25 % (7.5 – 12.5)	mV	

\*Note: Once you have entered the SENSITIVITY TEST, use F1: RESTART then F1: START to check the remaining settings.

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**b. VENTRICULAR CHANNEL**

(Use SigmaPace 1000 F4: >>>, F2: SENSE AMP, F2: VENTricular, F1: NEXT, F1: NEXT (DEFAULT SETTING: SSQ WAVE @ 40.0 mS WIDTH), F1: START (+ POLarity and 2.00 mV AMplitude)

Set pacemaker sensitivity as indicated below for each test.

Analyzer auto-advances

Operational Mode: VVI (Access this feature via the Medtronic 5388 Menu #1 or simply turn off the ATRIAL CHANNEL.)

Waveform: SSQ @ 40 mS

Rate @ 80 PPM

Atrial Channel: OFF and Ventricular Channel: ON

Ventricular Channel Output @ 10 mA

Sensitivity Setting	Specified Tolerance and Range (mV)	SigmaPace 1000 Reading	Status Pass / Fail?
0.8 mV*	± 0.25 mV (0.55 – 1.05)	mV	
2.0 mV	± 25 % (1.5 – 2.50)	mV	
4.0 mV	± 25 % (3.00 – 5.00)	mV	
12 mV	± 25 % (9.0 – 15.0)	mV	
20 mV	± 25 % (15 – 25)	mV	

\*Note: Once you have entered the SENSITIVITY TEST, use F1: RESTART then F1: START to check the remaining settings.

## 9. REFRACTORY PERIOD TEST

**a. ATRIAL CHANNEL**

(Use SigmaPace 1000 F4: >>>, F1: REFRACT DEMAND, F1: ATRial, F1: NEXT (DEFAULT SETTING = SQR WAVE and 1.00 mS WIDTH) , F1: NEXT (DEFAULT SETTING = + POLarity and 20.00 mV AMplitude)

Operational Mode: AAI

Selected Waveform: Square Wave @ 1.0 mS and 20 mV

Rate @ 80 PPM

Atrial Sensitivity Setting: 0.5 mV

Atrial Channel: ON and Ventricular Channel: OFF

Atrial Channel Output @ 10 mA

Refractory Period (RP) Test	Specified Setting and Tolerance (mS)	SigmaPace 1000 Reading	Status Pass / Fail?
Paced RP	250 ± 10 % (225 – 275)	mS	
Sensed RP	250 ± 10 % (225 – 275)	mS	

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**b. VENTRICULAR CHANNEL**

(Use SigmaPace 1000 F4: >>>, F1: REFRACT DEMAND, F2: VENTricular,  
 F1: NEXT (DEFAULT SETTING = SQR WAVE and 1.00 mS WIDTH) ,  
 F1: NEXT (DEFAULT SETTING = + POLarity and 20.00 mV AMPlitude)  
 Operational Mode: VVI  
 Selected Waveform: Square Wave @ 1.0 mS and 20 mV  
 Rate @ 80 PPM  
 Ventricular Sensitivity Setting: 2.0 mV  
 Atrial Channel: OFF and Ventricular Channel: ON  
 Ventricular Channel Output @ 10 mA

Refractory Period (RP) Test	Specified Setting and Tolerance (mS)	SigmaPace 1000 Reading	Status Pass / Fail?
Paced RP	250 ± 10 % (225 – 275)	mS	
Sensed RP	250 ± 10 % (225 – 275)	mS	

**10. OFF CURRENT DRAIN (PACEMAKER POWER OFF)**

(Use SigmaPace 1000 F4: >>> (2X), F2: DC LOAD,  
 F1: NEXT (Follow “ON-SCREEN” INSTRUCTIONS)

TURN PACEMAKER POWER OFF

Operational Mode: N/A  
 Atrial Channel: N/A  
 Ventricular Channel: N/A

POWER Status	Specified Tolerance (mA DC)	SigmaPace 1000 Reading	Status Pass / Fail?
Power OFF	0.15 Maximum	mA DC	

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## 11. ON CURRENT DRAIN (PACEMAKER POWER ON)

(Use SigmaPace 1000 F4: >>> (2X), F2: DC LOAD, F1: NEXT (Follow “ON-SCREEN” INSTRUCTIONS))

TURN PACEMAKER POWER ON

Operational Mode: DDD (Access this feature via the Medtronic 5388 Menu #1 or use it’s power up default output settings.)

Atrial Channel: ON and Ventricular Channel: ON

Atrial Channel Output @ 10 mA

Ventricular Channel Output @ 10 mA

POWER Status	Specified Tolerance (mA DC)	SigmaPace 1000 Reading	Status Pass / Fail?
Power ON (Wait 5 minutes) (Backlight OFF)	1.5 Maximum	mA DC	
Power ON (Wait 5 minutes) (Backlight ON)	20.0 Minimum	mA DC	

NOTES:

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*Note: This testing protocol is based upon the published Medtronic Model 5388 Temporary External Pacemaker checkout guide. Refer to the referenced Medtronic 5388 publication for additional details.*

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