

TESTING MEDTRONIC MODEL 5391 PACEMAKERS 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 5391 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.

5391 Service Life

Medtronic will no longer service or calibrate EPGs that are more than 5 years old. EPGs that are equal to or less than 5 years old can be serviced and calibrated.

Medtronic recommends that the 5391 have the calibration verified at minimum once every 12 months. When the 5391 reaches end of Medtronic Service Life, the 5391 can continue to be used, based on the physical condition and continued scheduled preventive maintenance checks (refer to the 5391 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 5391 Checkout Manual and the test results to be found within the stated tolerances of 5391 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 5391 Single 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 5391 tests are a compilation of the tests specified in the Medtronic 5391 Checkout procedure. 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. Where shown, values in parentheses represent “Hi-Lo” limits.

1. CHECK BATTERY.

- *-Always test a pacemaker using a “fresh” battery (9 volts ± 0.5 volts)*
- *-Turn on the pacemaker and observe completion of the self-test, after which the low battery symbol should **not** appear.*

Default settings for the 5391 are:

Rate = 72 bpm

Output = 6 Volts

Sensitivity = 2.0 mV

Pulse width = 0.75 ms (fixed or non-adjustable)

Refractory = 250 ms (fixed or non-adjustable)

Note:

The 5391 verification tests are performed through the Atrial channel of the analyzer. It is important to note, **“The Medtronic Model 5391 pacemaker is intended to be used in conjunction with a cardiac pacing lead system for temporary atrial or ventricular pacing in a clinical environment.”** The 5391 Checkout Manual references the Sensitivity and Refractory test to be set up for a P-Wave, ISO waveform of 2/13 ms width pulse. I have used a triangular or sin² waveform at 40 ms (25 Hz). Again, this is for Atrial channel testing purpose.

5391 Controls and Dials:

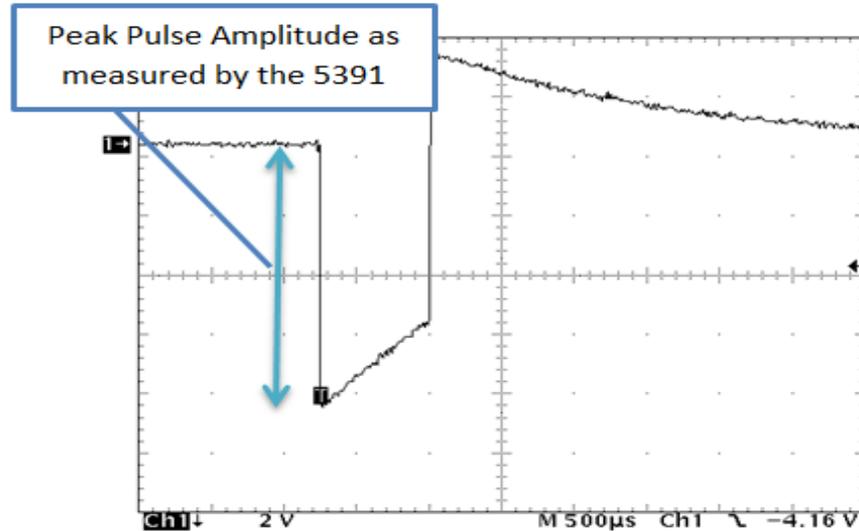
5391 (SSI) PACEMAKER	
1	Lead Terminals
2	Green LED – Sensed Event
3	Yellow LED – Paced Event
4	Pulse Output Amplitude (0.3 ... 12 V)
5	Mode Selector
6	Button to activate high-rate stimulation
7	Sensitivity Control
8	Stimulation Rate, ppm (Basic Rate)
9	Red LED – Errors, Low Battery
10	Cover
11	Ridge for Arm Strap



At this point it is important to present why there is a difference between the Output Pulse value being tested and the actual measurement for Output and Sensitivity.

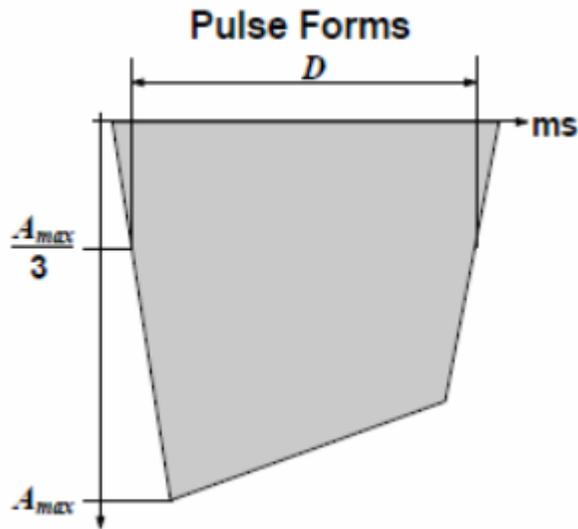
The 5391 uses a Triangular waveform, negative going in slope for ease of measurement which differs from ISO 5841-1, Sub clause B.2.2. The output voltage measurement is taken at 1/3rd the peak

of the output pulse. Tolerances are as follows, at 1 volt ($\pm 10\%$) at 2 volt and greater use $+10\%$ of the Nominally Measured Voltage.



The Model 5391 measures the output amplitude as the peak amplitude A_{max} (see mark in picture above). The Fluke Sigma 1000 however measures the amplitude according to ISO. That's why the nominal values and its tolerances need to be transferred from A_{PEAK} to A_{ISO} .

The figure below, from ISO 14708, shows a pulse form and the method to determine pulse duration at $1/3$ of the max. Pulse amplitude.



**** Refer to page 6 of the 5391 Checkout Manual for mathematical explanation of measuring the Output Pulse.**

Rate – Output – Pulse Width Test for the 5391

Set-up for the SigmaPace 1000 and 5391:

DEMAND MODE: Verify operation as a “demand” “AAI” pacemaker, i.e. pacing is inhibited in the presence of an intrinsic ECG signal.

- Power-up, the 5391 pacemaker.
- Set 5391 pacer to a Rate of 70 and set the output to 6 volts.
- Connect the FLUKE SigmaPace 1000 atrial channel test leads to the 5391 pacer. Per Fig 1
- Depress “ENT/POWER ON” button on the FLUKE analyzer.
- Depress “F2” (INV) to select the “Invasive” category. Figure 2
- Depress “F1” (NEXT) to accept a 500 Ohm load as a test load. Figure 3
- Depress “F1” (PULSE OUTPUT). Figure 4
- Depress “F2” (Atr Only) to test. Figure 5
- Depress “F1” (START).

Note: All images or Figures stated throughout this document are **only** for reference and not intended for actual numerical values.

- The analyzer will perform a brief calculation, and then it will begin to display the pacer’s (5391) set RATE along with values for “Volts”(Output), ”Rate”(ppm), “Width” (Pulse width) . Figure 5.

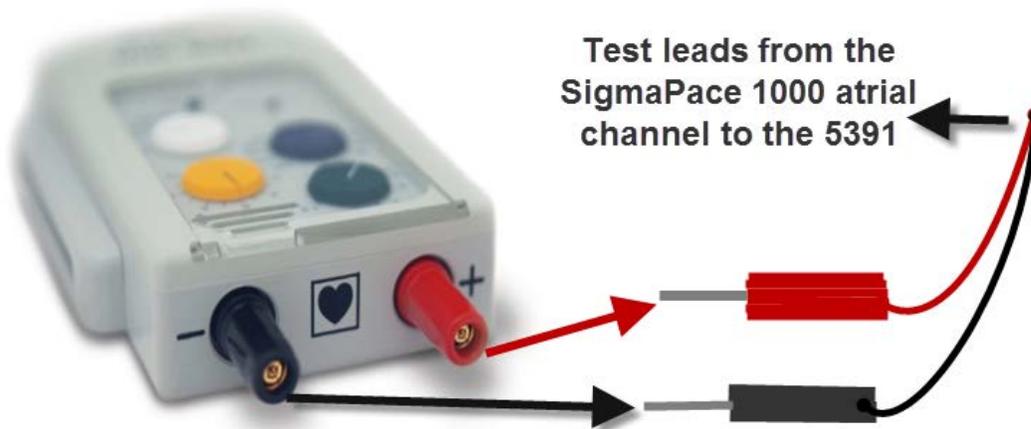


Figure 1

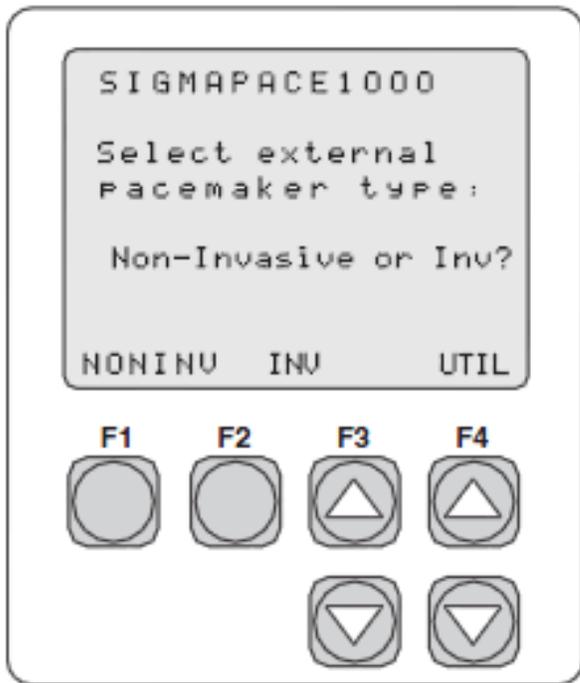


Fig 2

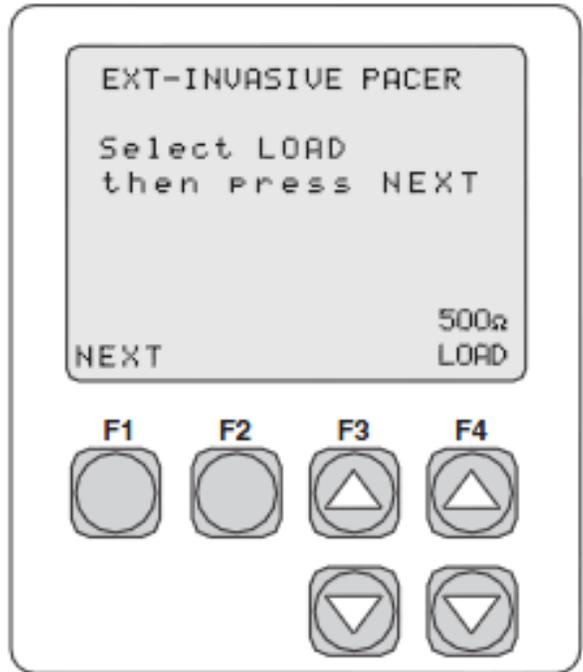


Fig 3

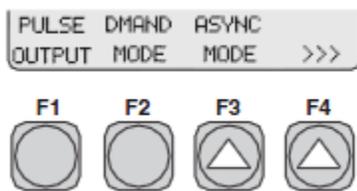


Fig 4

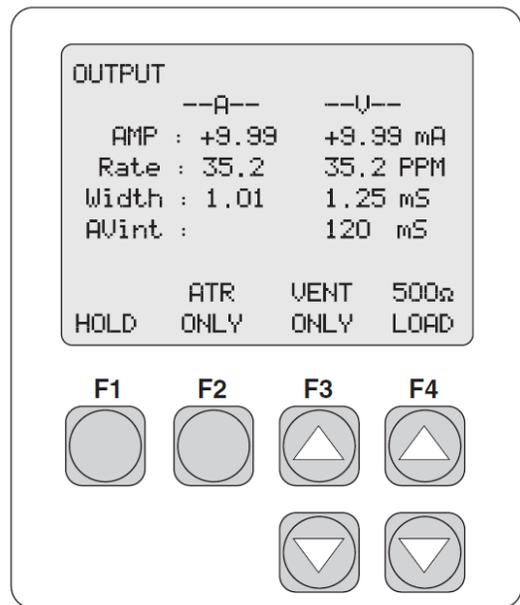


Fig 5

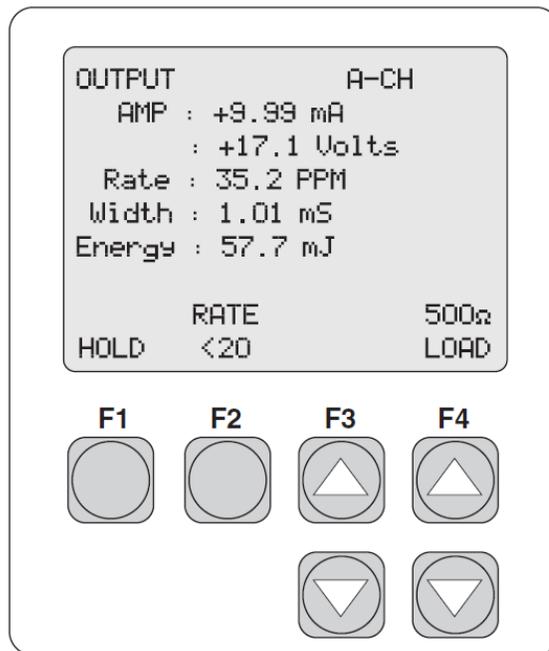


Fig. 6

1. PULSE OUTPUT TEST:

Verify Accuracy of RATE (BPM), OUTPUT (volts), Rapid Atrial Pacing (RAP) and PULSE WIDTH (ms) for the 5391 pacemaker. Figure 6, above.

- Tolerance of test points is 10%
- Set 5391 pacer as follows and compare settings to measured test values:

<u>Ch.</u>	<u>Rate = BPM</u>		<u>Output (O/P) = volts</u>		<u>Pulse Width = ms</u>	
	<u>Set Rate</u>	<u>(Result Range)</u>	<u>Set O/P</u>	<u>(Result Range)</u>	<u>Spec. Pulse Width</u>	<u>(Result Range)</u>
A	30	(27 - 33)	1.0	(0.719 – 0.901)	0.75	(0.70 – 0.80)
A	60	(54 – 66)	2.0	(1.457 – 1.803)	0.75	(0.70 – 0.80)
A	100	(90 - 110)	4.0	(2.924 – 3.596)	0.75	(0.70 – 0.80)
A	100	(90 - 110)	8.0	(5.858 – 7.182)	0.75	(0.70 – 0.80)
A	100	(90 - 110)	10.0	(7.316 – 8.964)	0.75	(0.70 – 0.80)
A	180	(162 - 198)	12.0	(8.783 – 10.757)	0.75	(0.70 – 0.80)

RAPID ATRIAL PACING Test: (Optional)

***Complete Rapid Atrial Pacing test from the “Pulse Output” Test Screen on the SigmaPace 1000. The rate is the only change that would be observed on the SigmaPace screen*



Figure 7



Figure 8

Verify that only the Rate changes and that the Amplitude, Pulse Width remains the same.

To test for Rapid Atrial Pacing on the 5391:

- Using the mode dial (Fig. 8) set the 5391 to x2 or x4. The 5391 will continue to operate at the rate set as in Fig. 7.
- To activate Rapid Atrial Pacing press and hold down the “High Rate” button, as seen in Fig. 8
- To determine the rate for RAP look at the base rate and the setting on the mode control at x2 or x4. Determine the rate by multiplying base rate times x2 = R.A.P.
 - Example: Base rate = 70
Mode setting = x2
R.A.P. = 140 ppm (Rapid Atrial Pacing Rate)

*At x4 the RAP rate would be base rate of 70 times 4 equaling a Rapid Atrial Pacing rate of 280 **once** the High Rate button is depressed.*

***Note:** Once the High Rate button is released the rate will return to the base rate of 70, as in Figure 7, above.*

Sigma Pace 1000 Rapid Atrial Pacing Test Setup:

- From the “Pulse Output” test screen on the Sigma Pace 1000, Fig. 6
- Measurements for Rapid Atrial Pacing will be seen in the rate category.

Tolerance of RAP measurement is 10%

- at x2 and rate set to 80 range is 144 ppm – 176 ppm, (nominal measurement is 160 ppm)
- at x4 and rate set to 80, range is 288 ppm – 352 ppm, (nominal measurement is 320 ppm)

Rapid Atrial Test:

- Set the 5391 rate to 80
- Turn mode control to x2
- Press and hold the “High Rate” button
- Value measured on the SigmaPace 1000 should be “rate = 160”, at a setting of x2 ($\pm 10\%$)
- Turn the mode control switch on the 5391 to x4 and measure the rate.
- Measurement on the SigmaPace 1000 should read “320 ppm” ($\pm 10\%$)

Note: When RAP testing is completed, press the “ESC” button 2 times, on the SigmaPace 1000, to go back to the main menu screen.

2. SENSITIVITY TEST:

Demand Mode is identified by adjusting the Sensitivity dial, of the 5391, to 1 mV. Refer to Fig D, below, for a screen shot.

Atrial SENSITIVITY is tested using a “Positive Polarity” (“+P”) test waveform, on a SigmaPace 1000 analyzer.

Note: The P wave is from an Atrial QRS complex.

Optional: Testing may be repeated using a “Negative Polarity” test waveform. To perform refer to Fig. 8 and using the up arrow below “F3” to change polarity of test. Again to test sensitivity in the opposite polarity is not required. Only testing sensitivity in either a positive or negative phase is required.



Fig. D

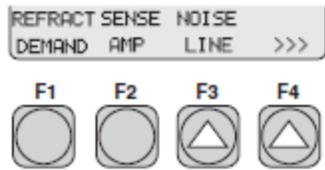


Fig. 5

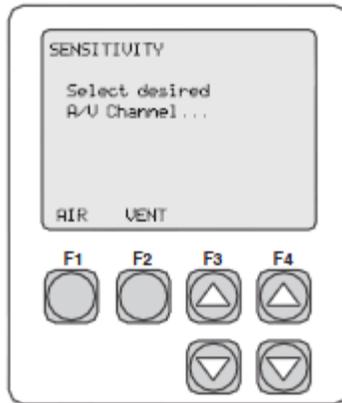


Fig. 6

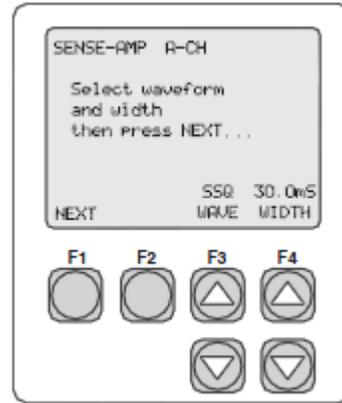


Fig. 7

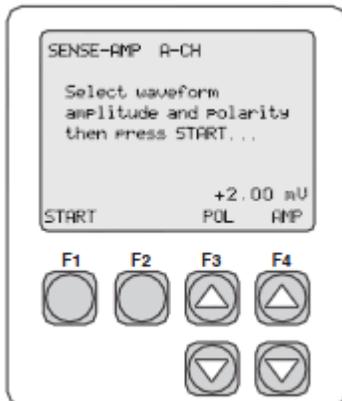


Fig 8

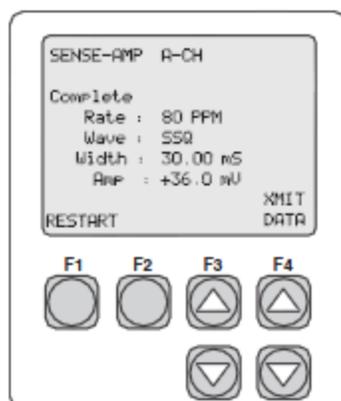


Fig 9

5391 Sensitivity Test:

5391 Sensitivity Test Set-up: refer to (Fig. D)

- *Rate = 60 bpm*
- *V Output = 6 volts*
- *Adjust 5391 Sensitivity dial to 5 mV.*

SigmaPace 1000 Test Set-up:

******Connect the Atrial test leads from the SigmaPace 1000 to the 5391.**

On the FLUKE, return to the main Menu screen by pressing the “Esc” key. If at the main menu, of the SigmaPace, as in Fig. 3, press F4 “>>>” to forward to the next menu screen.

- *Press F2 “Sense Amp” test. Figure 5*
- *Select F1 “Atr” per Fig 6.*
- *Press “F1” (NEXT) to accept a 500 Ohm load.*
- *Using the F3 “arrow UP” to **ISO Wave 2/13 ms width**, then Press “F1” (NEXT).*
- *Press “F4” down arrow to decrease “AMP” (test amplitude) to .05mV. Fig. 8*
- *Press “Start” to begin the test.*
- *To test at the additional test points below, adjust the sensitivity control knob, on the 5391, to the next test point then press “restart” on the SigmaPace analyzer. Depress the FLUKE “F1” (START) key; the test will pick up at the last value measured – a time-saver. --Repeat as required.*

Sensitivity Test Tolerance = 20%

<u>5391 Sensitivity Test Set-up;</u>	<u>Tolerance</u>	<u>SigmaPace 1000 “Amp” starting point</u> (refer Fig 8 above)
5.0 mV Atrial	4.00 – 6.00	+ .05 mV
10 mV Atrial	7.50 – 12.5	+ 3.0 mV
20 mV Atrial	15.0 – 25.0	+ 10.0 mV

The variability of measurement when testing sensitivity is based on the waveform being used. When testing the 5391 Sensitivity waveform and width on the SigmaPace 1000 can be set to use the following frequencies for an Sine Square waveform :

- 15 ms pulse duration $S_{\sin 2} 15 \text{ ms} = 0.77 S_{\text{ISO}}$ - (with the 5391 sensitivity set to 1 mV)
- 25 ms pulse duration $S_{\sin 2} 25 \text{ ms} = 0.83 S_{\text{ISO}}$ - (with the 5391 sensitivity set to 1 mV)
- 40 ms pulse duration $S_{\sin 2} 40 \text{ ms} = 1.19 S_{\text{ISO}}$ - (with the 5391 sensitivity set to 1 mV)

3. REFRACTORY PERIOD: (optional)

Objective:

- Verifies “Sensed Refractory Period” (SRP) and “Paced Refractory Period” (PRP).
- Verify that the analyzer results fall within the acceptable ranges below.
- Refractory is non-adjustable and **programmed** to 250 ms.

Note: When using the Fluke Biomedical SigmaPace 1000 you may need to add 13 ms to the SRP value measured.

SRP / PRP Refractory periods.

Refractory Test Tolerance = 5%

	<u>Value</u>	<u>Tolerance</u>
ATR PRP:	250ms	(237 - 263)
ATR SRP:	250ms	(237 - 263)

Atrial Refractory PRP / SRP Test

5391 Set-up:

Rate = 70

Output = 6 volts

Mode = ISO 2/13/ ms

Sensitivity = 10.0 mV

SigmaPace 1000 Set – up:

- Go to the Main Menu of the SigmaPace 1000:
 - *** If at the completion of the “sense amp” test press “Esc” 3 times to go to the main menu. Fig 10
 - *** From the power on state for the SigmaPace, go to the main menu and press “F4”. Fig 3
- Press “F1” (Refractory Demand).
- Press “F2” for “Atr”. (Fig 11)
- Using the down arrow under F3, (Fig 12), go to ISO 2/13 mS. and use the 1 mS. width, above F4.
- Press “F1” again for (Next). Fig 13
- Amplitude (“amp”, above F4 will display 20 mV and above F3 “+” for a positive going pulse.
- Press “F1” (START). Wait for results... Fig. 13

Note: When using the Fluke Biomedical SigmaPace 1000 you may need to add 13 ms to the SRP value measured.

END of test

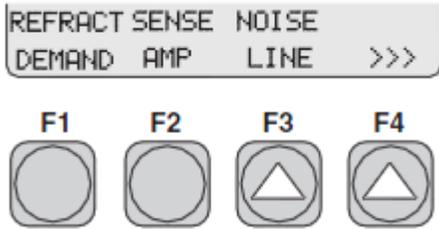


Fig 10

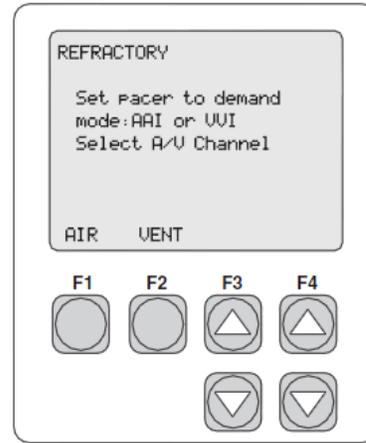


Fig 11

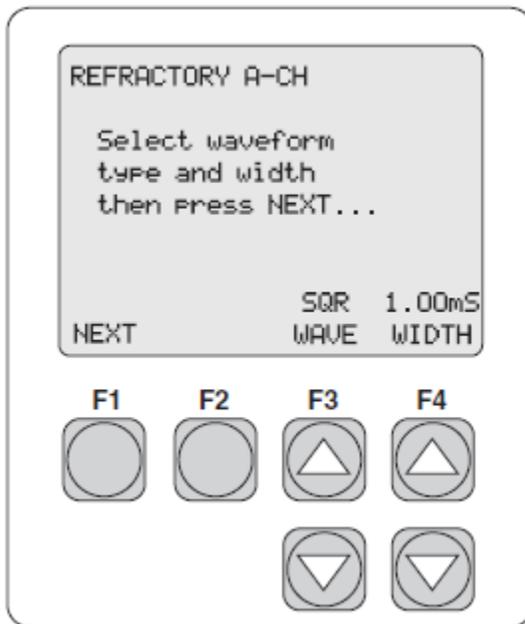


Fig. 12

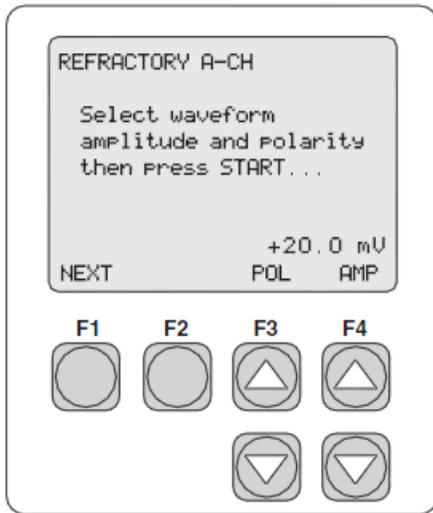


Fig 13

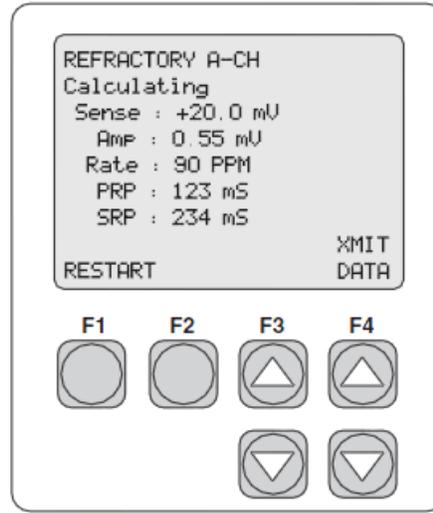


Fig 14

The analyzer can perform more intensive tests, but those are beyond the scope of “Routine Preventative Maintenance”.

Connecting SigmaPace 100 Test Leads to the 5391:

There are 2 options when connecting test leads to the 5391:

- 1) Use the 5433 or 5433A Patient Cable and connect test leads to the connector block and tighten using thumbwheels. Insert each pin into the proper receptacle (marked + and -). Fig. 16
- 2) Connect the test leads to the 5391 using the device connector post. Insert each test into the proper receptacle (marked + and -). Fig. 15

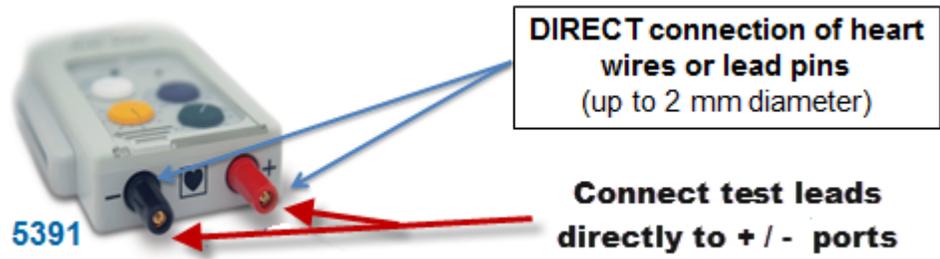


Fig. 15

Direct connect or use Adapter/Extension

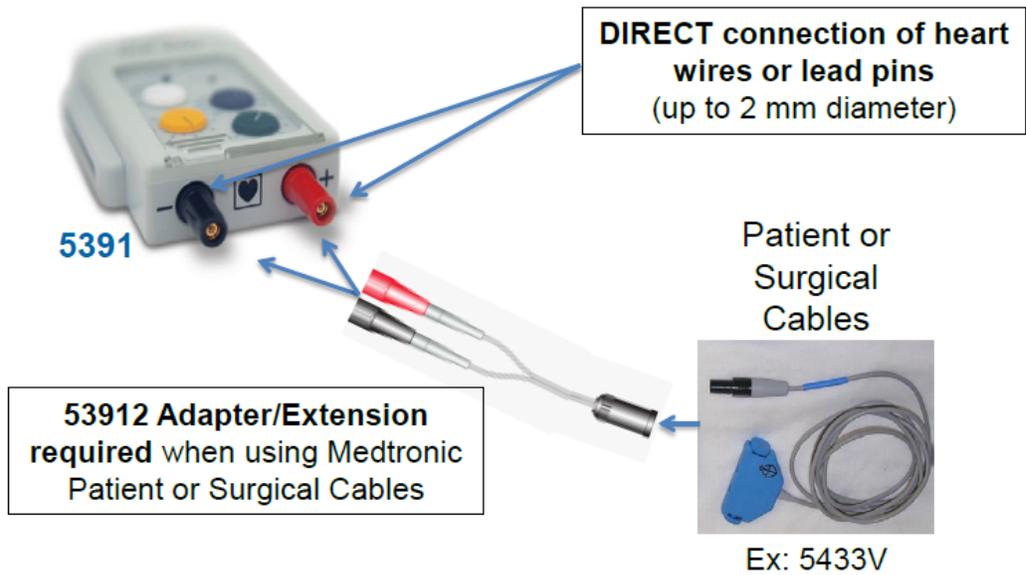
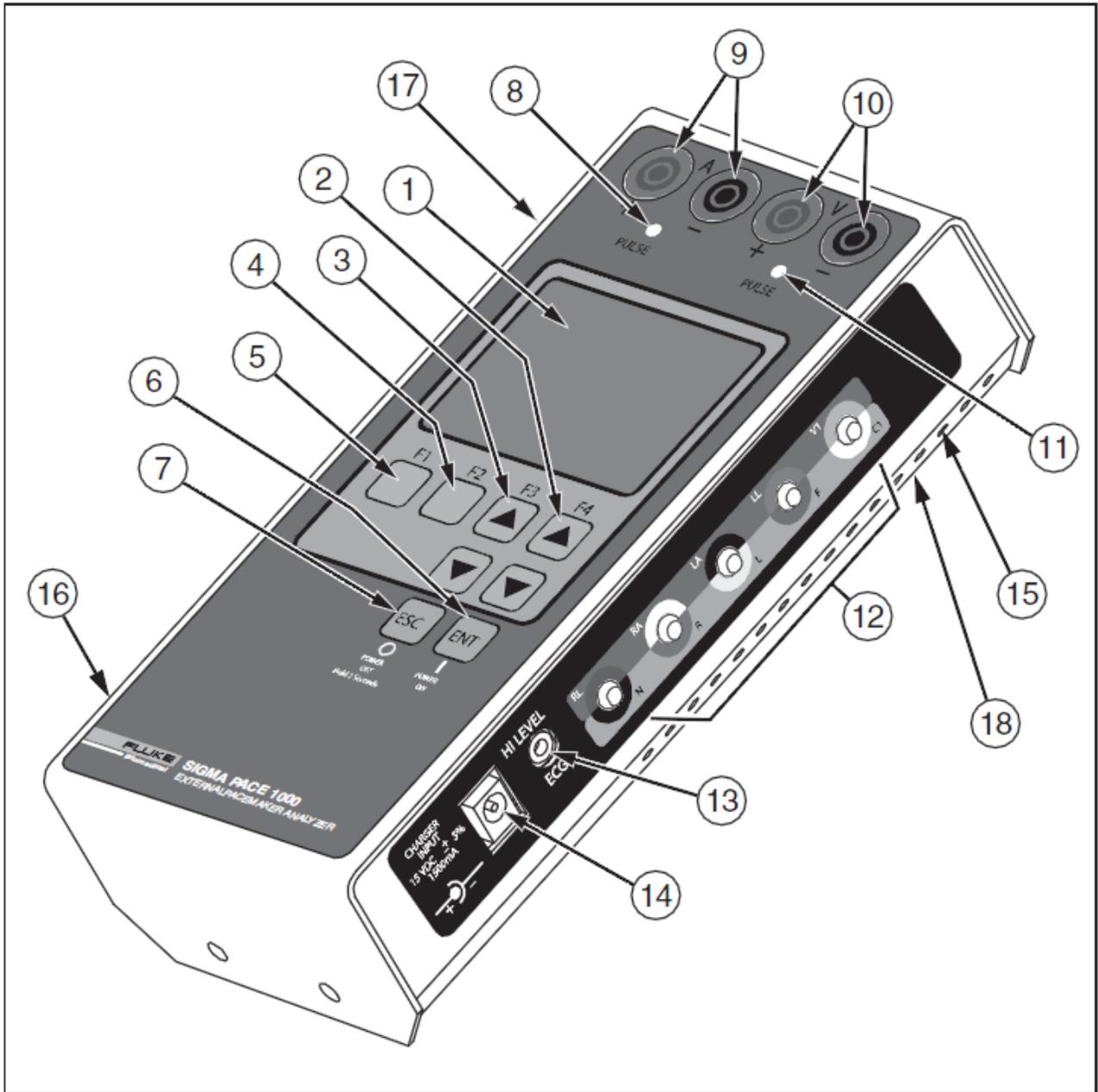


Fig. 16

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.

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.

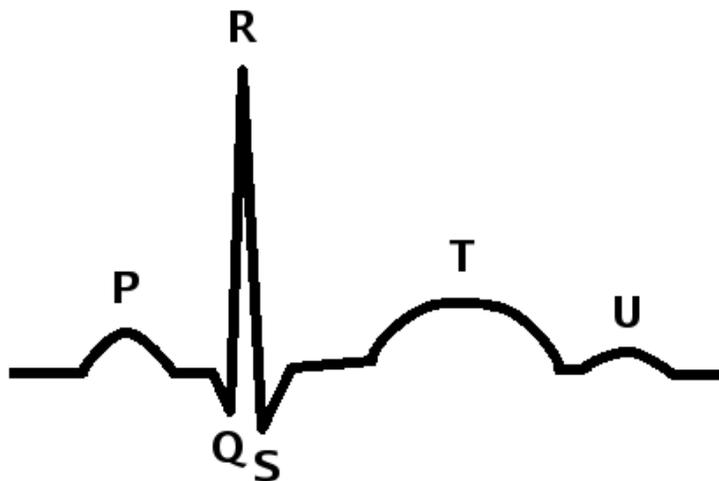
Sensed Refractory Period (SRP)

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.

To Inhibit while Pacing

In the presence of patients intrinsic or natural R wave or P wave (Found in the QRS complex), the 5391 not pace and the pacing L.E.D. will go off. The sense L.E.D. will start flashing, indicating that the patients intrinsic P wave or R wave is present.

The QRS Complex



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