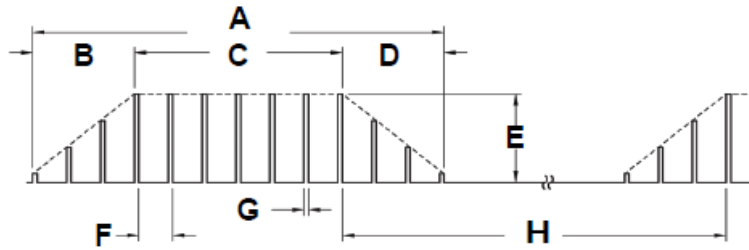


Figure 12. Stimulation (Frequencies <10 Hz do not ramp)



- A** Stimulation Time
- B** Ramp Up (2 sec.)
- C** On Time
- D** Ramp Down (2 sec.)
- E** Output Current
- F** 1/Signal Frequency
- G** Pulse Width
- H** Off Time



Caution: Possible nerve damage with ON time \geq OFF time— Stimulation in which ON time exceeds OFF time for more than 8 hours has resulted in degenerative nerve damage in laboratory animals. Such excessive stimulation can be produced by continuous or frequent magnet activation.

3.4.2.1.9. Duty cycle

The percentage of time the pulse generator is stimulating is called a “duty cycle.” A duty cycle is calculated by dividing the stimulation time (programmed ON time plus, if frequency is ≥ 10 Hz, 2 seconds of ramp-up time and 2 seconds of ramp-down time) by the sum of the ON and OFF times. The various parameter settings for stimulation are listed in “Specifications and Product Information”.

Table 10 shows duty cycles for typical ON time and OFF time settings.

Table 10. Duty Cycles for Various ON and OFF Time Settings

	OFF Time (min)								
	0.2	0.3	0.5	0.8	1.1	1.8	3	5	10
ON Time (sec)	Duty Cycles* (% ON Time)								
7	58	44	30	20	15	10	6	4	2
14	69	56	41	29	23	15	9	6	3
21	76	64	49	36	29	19	12	8	4
30	81	71	57	44	35	25	16	10	5
60	89	82	71	59	51	38	27	18	10

* A duty cycle is calculated by dividing stimulation time (programmed ON time plus 2 seconds of ramp-up time and 2 seconds of ramp-down time) by the sum of the ON time and the OFF time.

3.4.1. Specifications and Product Information

The specifications and product information for the VNS Therapy pulse generators are presented in Table 9.

Table 9. Specifications and Product Information

Stimulation Parameters	Available Parameter Settings
Output current	0-3.5 mA in 0.25-mA steps $\pm 0.25 \leq 1$ mA, $\pm 10\%$ > 1 mA
Signal frequency	1, 2, 5, 10, 15, 20, 25, 30 Hz $\pm 6\%$
Pulse width	130, 250, 500, 750, 1000 μsec $\pm 10\%$
Signal ON time	7, 14, 21, 30, 60 sec $\pm 15\%$ or +7 sec, whichever is greater ($\pm 15\%$ or ± 7 sec in Magnet Mode)
Signal OFF time	0.2, 0.3, 0.5, 0.8, 1.1, 1.8, 3 min, and 5 to 180 min (5 to 60 in 5-min steps; 60 to 180 in 30-min steps) +4.4 / -8.4 sec or $\pm 1\%$, whichever is greater
Magnet activation	Provided by magnet application (output current, pulse width, and signal ON time may be independently programmed for this purpose)
Reset parameters	Settings are unchanged, but output is disabled (0.0mA)
Telemetry Reports	
Device History Report	Patient ID, implant date, model number, serial number, magnet activations, total ON time, total operating time, and manufacturing date
Device Diagnostic Report	Patient ID, model ID, serial number, implant date, communication status, output current status, measured current delivered, lead impedance, and battery status indicators (IFI, N EOS, EOS)