



## Dosing



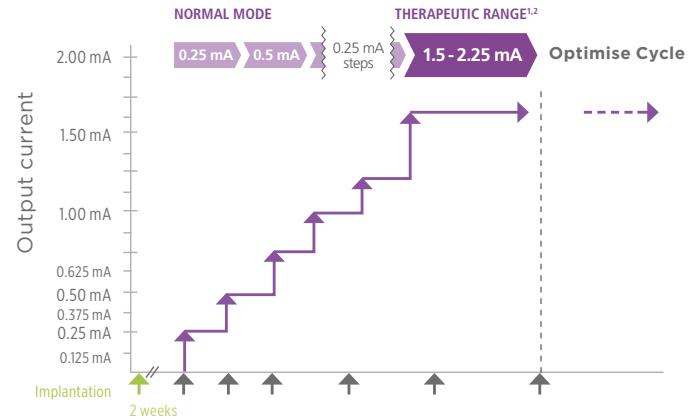
# Optimising Programming

## Objective 1 - Increase Output Current

### Suggested Initial Programming Settings

Normal	Output Current	0.25 mA
	Frequency	30 Hz
	Pulse Width	250 µsec
	DUTY CYCLE: 10%	
	ON Time	30 sec
	OFF Time	5 min
Magnet	Output Current	0.5 mA
	ON Time	60 sec
	Pulse Width	250 µsec

### Optimise Output Current



Multiple 0.25 mA increases may be made in a single visit to reach therapeutic range sooner; ensure patient tolerability before making additional adjustments.

### Dosing Notes

- Continue to optimise dose to therapeutic effect or tolerability
- Give patient time to adapt to parameter changes before making additional adjustments

# Optimising Programming

## Objective 2 - Optimise Seizure Response

### Initial Settings for Responsive VNS Therapy

(with AspireSR & SenTiva)

AutoStim	Output Current	Equal to normal mode settings*
	Pulse Width	
	ON Time	
Seizure Detection		ON
Heartbeat Detection	Sensitivity Range 1-5	Verify by comparing the heart rate shown on the VNS Therapy programming system with that measured by a heart-rate sensing device. If the heartbeat detection is inaccurate, adjustments of heartbeat detection sensitivity may be needed <sup>3</sup> .
Threshold for AutoStim	% heart rate change Range 20-70%	Refer to detection threshold below

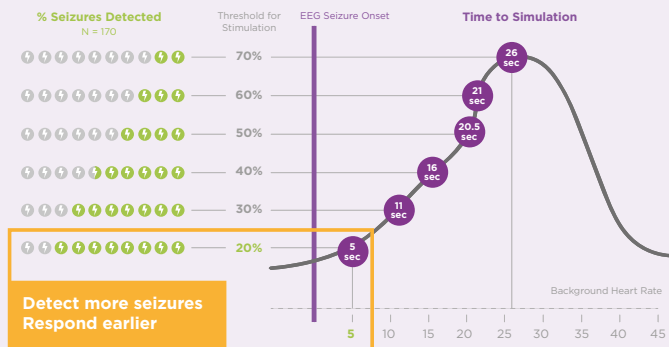
\* AutoStim can be set 0.125 mA higher during titration phase to accustom patient to the next output current level.

## Detection Threshold

The initial seizure response threshold may be set at 20%

- The threshold (20-70%) determines the relative heart rate increase that will trigger AutoStim, thereby also influencing detection latency<sup>4</sup>.
- Ensure early, tolerable and reliable seizure detection in patients with seizures associated with ictal tachycardia.

### Example seizure with heart rate increase



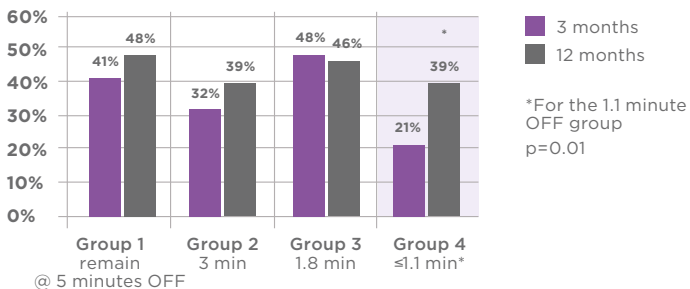
# Optimising Programming

## Objective 3 - Optimise Duty Cycle

- Higher total daily charge of VNS was associated with significantly higher response rates in children with refractory epilepsy.<sup>5</sup>

### Median Seizure Reduction by Duty Cycle:

All groups initially received VNS Therapy with 5 minutes OFF. Groups 2-4 were then switched to shorter OFF times at 3 months and evaluated at 12 months.<sup>6</sup>

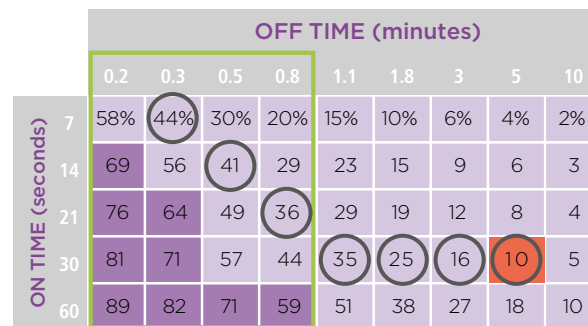


In patients with low response to VNS Therapy with 5 minutes OFF, reducing the OFF time to 1.1 minutes or less significantly increased seizure reduction.

### Standard Duty Cycle (DC) is 10%

(30 sec ON and 5 min OFF)

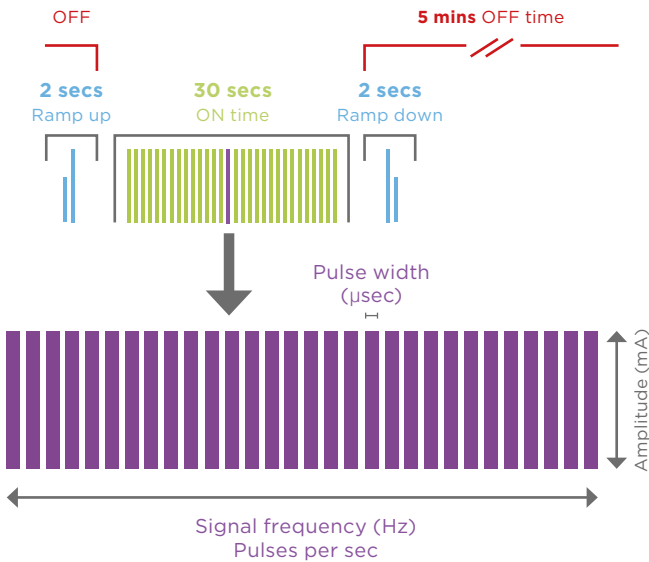
- After 3 months, consider increasing the DC to greater than 20% (typically, decreasing the OFF time to ≤1.1 minutes). Nevertheless, adjustments to DC should be less frequent (3 - 6 months).<sup>2</sup>



- Recommended
- Not recommended \*
- Recommended progression for duty cycle
- Not available if Cardiac Based Seizure Detection (CBSD) feature is enabled

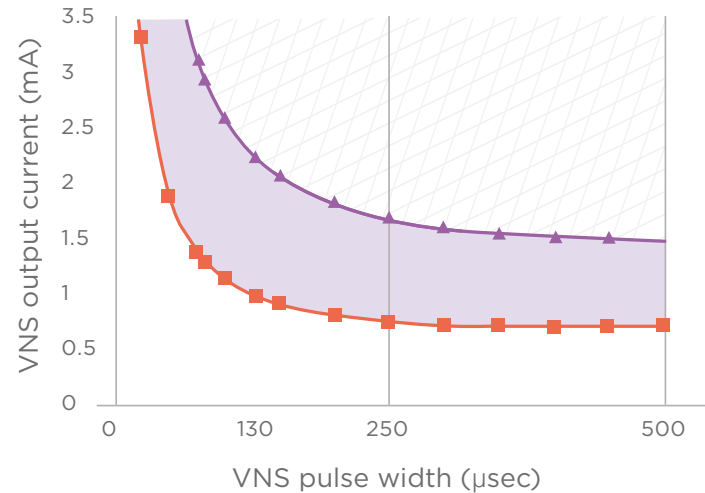
# Stimulation Parameters

## Stimulation Parameter Example



## Strength-Duration Curve for VNS<sup>1</sup>

Example only - individual titration required\*



■ Intra Op Stimulation S-D Curve

▲ Clinical Response

\* Output current above the purple line may decrease battery life and have unnecessary side effects.

Output Current below the orange line may be subtherapeutic.

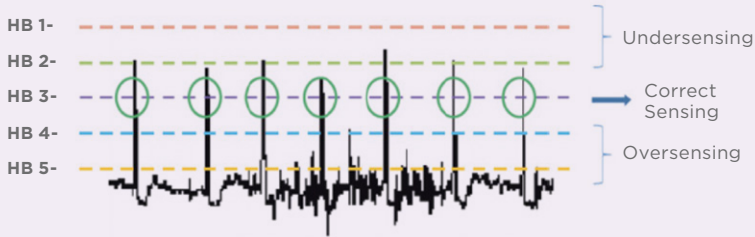
# Sensitivity Calibration

## Optimising VNS Settings

### The initial sensitivity level may be set at HB 1 but adjusted if necessary

(See VNS Therapy Physician's Manual).

#### Example:



**Undersensing** (reduced or inconsistent detection)

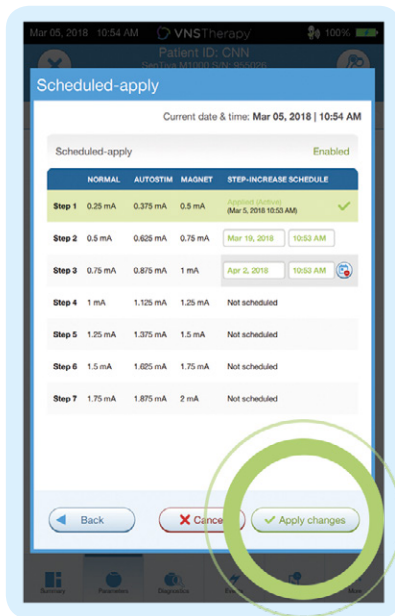
**Oversensing** (additional detection of “noise” between heartbeats)

- To ensure **reliable sensing** of the patient’s heartbeat a correct heartbeat detection sensitivity (HB 1-5) is crucial.
  - **HB 1** is the least sensitive heartbeat detection setting and is most prone to undersensing due to potentially not sensing each R-wave.
  - **HB 5** is the most sensitive heartbeat detection setting and is most prone to oversensing due to potential sensing of “noise”.
- If no presurgical evaluation has been performed, find the most appropriate heartbeat setting (1-5) that delivers accurate heart rate measurements when patients are standing up and lying on left side. For this compare the heartbeat measured by the VNS Therapy programming system to that displayed on a heart rate monitoring device.



# Customisable Programming Features

## Scheduled Programming (SenTiva® Only)



## Day & Night Mode (SenTiva® Only)



# Side Effects Management

Side Effects Management	
1. Pulse Width	500 → 250 µsec
2. Signal Frequency	30 → 25 or 20 Hz
3. Reduce Duty Cycle	30 sec ON/5 min OFF versus 7 sec ON/1.8 min OFF
4. Output Current	↓ 0.125 mA or ↓ 0.25 mA

Additional Options for AspireSR <sup>®</sup> and SenTiva <sup>®</sup>	
1. Verify Heartbeat Sensitivity Calibration	Adjust Heartbeat Sensitivity, if necessary
2. Output Current	AutoStim mode: ↓ 0.125 mA
3. Threshold for AutoStim	If patient reports "overstimulation": Autostim Threshold ↑ 10% If patient reports "understimulation": Autostim Threshold ↓ 10%

\* LivaNova recommends that stimulation with Normal Mode ON time > OFF time be avoided. Duty Cycle = (ON Time + 4 seconds) / (ON time + OFF Time), for which ON and OFF Time are measured in seconds.





#### References:

1. Helmers SL, et al. Acta Neurol Scand 2012; 126(5):336-43
2. Heck C, Helmers SL, DeGiorgio CM. Neurology 2002; 59 (6 Suppl 4):S31-7
3. Data on File, LivaNova, Houston, TX
4. Bialer M et al. Epilepsy Research 2017; 130: 27-36
5. Orosz, I et al. Epilepsia 2014; 55(10): 1576-84
6. DeGiorgio CM et al Epilepsia 2001; 42: 1017-1020

#### Additional Information

Please see important safety information at [www.VNSTherapy.com](http://www.VNSTherapy.com)

This information is not intended to serve as a substitute for a complete and thorough understanding of the material presented in the Physician's Manuals for the VNS Therapy system and its component parts and does not represent full disclosure of all pertinent information concerning the use of this product, potential safety complications, or efficacy outcomes.

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