VNSTherapy®

AspireSR® Generator

AspireSR GENERATOR MODEL 106

The Model 106 has the same circuitry and high capacity battery as the Model 105, with an added feature that provides responsive stimulation to heart rate increases that may be associated with seizures.

COMPATIBILITY

Model 106 is compatible with these system components:

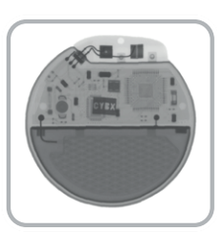
COMPONENT	MODEL
Lead	302, 303, 304
Wand	201
Tablet Software	250 v 11.0
Tunneler	402
Accessory Pack	502
Magnets	220

GENERATOR SPECIFICATIONS

The VNS Therapy System conforms to these standards:

- EN 45502-1 — Active implantable medical devices — Part 1: General requirements for safety, marking and information to be provided by the manufacturer

Stimulation Parameters	Available Parameter Settings
Output current	0-2.0 mA in 0.125 mA steps 2.0-3.5 mA in 0.250 mA steps (+0.1 mA or +10%; whichever is greater)
Signal frequency	1, 2, 5, 10, 15, 20, 25, 30 Hz 36%
Pulse width	130, 250, 500, 750, 1000 µsec 310%
Signal ON time	7, 14, 21, 30, 60 sec Normal Mode (+7sec/-15%) Magnet Mode (+15%/-7sec) AutoStim Mode (+15%/-7sec)
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 sec or +/-1%, wichever is greater
Magnet activation	Provided by Magnet application (output current, pulse width, and signal ON time may be independently programmed for this purpose)
AutoStim	Automatic Tachycardia Response (output current, pulse width, and signal ON time may be independently programmed for this purpose) In addition, Seizure Detection, Heartbeat Sensitivity and Threshold for AutoStim 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)

Physical Characteristics - Materials

Case	Titanium, hermetically sealed
Header	Polyurethane — Tecothane TT-1075D-M Thermoplastic
Lead connector blocks	Stainless steel
Setscrew plug	Silicone (Latex is not included in any component of the VNS Therapy System)

Power Source

Chemistry	Lithium carbon monofluoride
Voltage	3.3 V, open circuit
Rated capacity	1.7 Amp-hour
Self-discharge rate	<1% per year

Measurements (Typical)

Lead receptacle	0.126 in (3.2 mm) nominal
Dimensions (52 mm x 52 mm x 6.9 mm)	2.0 in x 2.0 in x .27 in
Weight	0.88 oz (25 g)

Connector Retention Strength

With VNS Therapy Lead	>10N

VNS THERAPY EUROPEAN INDICATION FOR USE

VNS Therapy is indicated for use as an adjunctive therapy in reducing the frequency of seizures in patients whose epileptic disorder is dominated by partial seizures (with or without secondary generalization) or generalized seizures that are refractory to seizure medications. The Model 106 AspireSR® (Seizure Response) features the Automatic Stimulation Mode, which is intended for patients who experience seizures that are associated with cardiac rhythm increases known as ictal tachycardia.

CONTRAINDICATIONS:

The VNS Therapy system cannot be used in patients after a bilateral or left cervical vagotomy. Do not use short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy on patients implanted with the VNS Therapy system. Diagnostic ultrasound is not included in this contraindication. Cardiac arrhythmia (Model 106 only)—The AutoStim Mode feature should not be used in patients with clinically meaningful arrhythmias or who are using treatments that interfere with normal intrinsic heart rate responses.

WARNINGS:

Physicians should inform patients about all potential risks and adverse events discussed in the VNS Therapy Physician Manuals, including information that VNS Therapy may not be a cure for epilepsy. Since seizures may occur unexpectedly, patients should consult with a physician before engaging in unsupervised activities, such as driving, swimming, and bathing, or in strenuous sports that could harm them or others.

A malfunction of the VNS Therapy system could cause painful or direct current stimulation, which could result in nerve damage. Removal or replacement of the VNS Therapy system requires an additional surgical procedure. Patients who have pre-existing swallowing, cardiac, or respiratory difficulties (including, but not limited to, obstructive sleep apnea and chronic pulmonary disease) should discuss with their physicians whether VNS Therapy is appropriate for them since there is the possibility that stimulation might worsen their condition. Postoperative bradycardia can occur among patients with certain underlying cardiac arrhythmias. MRI can be safely performed; however, special equipment and procedures must be used.

ADVERSE EVENTS:

The most commonly reported side effects from stimulation include hoarseness (voice alteration), paresthesia (prickling feeling in the skin), dyspnea (shortness of breath), sore throat and increased coughing. The most commonly reported side effect from the implant procedure is infection.

*The information contained here represents partial excerpts of important prescribing information from the product labeling. Patients should discuss the risks and benefits of VNS Therapy with their healthcare provider. Visit www.VNSTherapy.com for more information.

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AspireSR® is CE mark approved and commercial distribution may vary by country.

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