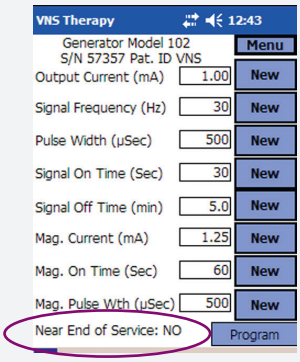
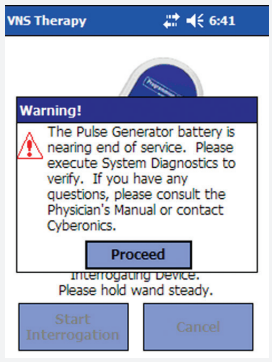
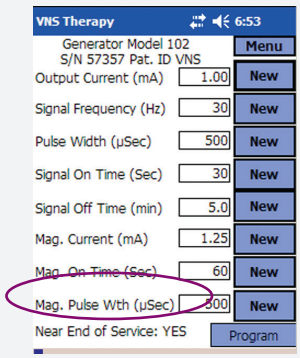
VNSTherapy®

Battery Status
Pulse™ (Model 102/102R)

Monitoring battery status is critical to ensuring continuation of treatment. Battery status is classified under two categories: Normal and Near End of Service (NEOS).

Status	NEOS Flag	Recommendation
Normal (NEOS = NO)		The generator battery level is good. No special attention is required. Generator replacement is not required, unless for prophylactic reasons.
NEOS (NEOS = YES)	 	The battery charge is low. The programming software will display a warning message indicating this status upon completion of interrogation or diagnostic testing. It is recommended that the generator be replaced as soon as possible. If the generator is not promptly replaced, it will reach "End of Service" (EOS). Potential adverse events associated with EOS may include, but are not limited to: • increase in seizure activity • painful or erratic stimulation • reports of decreased perception of stimulation • no stimulation when performing daily magnet activation Additionally, once EOS has been reached, the generator will lose the ability to communicate with the programming system. ***The time from NEOS to EOS is highly dependent on the programmed settings and lead impedance.***

Please refer to the VNS Therapy Physician's Manuals for complete information on battery longevity.
VNS Therapy Physician's Manuals. Cyberonics, Inc.; Houston, Texas.

For full prescribing and important safety information, please visit **www.VNSTherapy.com** or ask your VNS Therapy representative.

VNS Therapy®

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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