

# Characterizing Rechargeable IPG Charge Cycle Time in DBS

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Published: North American Neuromodulation Society (NANS) 2013 Poster.

Device Utilized: Zero-Volt™ Batteries

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Yu, X, et al. (2013). Characterizing rechargeable IPG charge cycle time in DBS. North American Neuromodulation Society (NANS) 2013.

## Background

Rechargeable Deep Brain Stimulation (DBS) Implantable Pulse Generators (IPGs) have different battery capacities, which result in differing recharge intervals. Three tests were conducted to characterize the discharge cycle of the Vercise™ IPGs during various use models.

The use models included a standard amplitude, using typical clinical IPG parameters; a high amplitude, which doubled the current, compared to the standard settings; and a low amplitude model, which halved the current, compared to the standard settings.

## Methods

- Standard set-up consisted of a Vercise IPG with two leads attached, in a saline solution at 37°C
- Stimulation settings were 60 µs pulses at 130 Hz, providing current through two cathodic contacts, one on each lead, using the immersed case as the anode
- IPGs were interrogated with the Remote Control (RC) 3 times a week to simulate patient interaction

### Standard Treatment Parameters

N = 7  
Amplitude: **3.0** milliamps  
Pulse Width: 60 µs  
Frequency: 130 Hz

### High-Amplitude Treatment Parameters

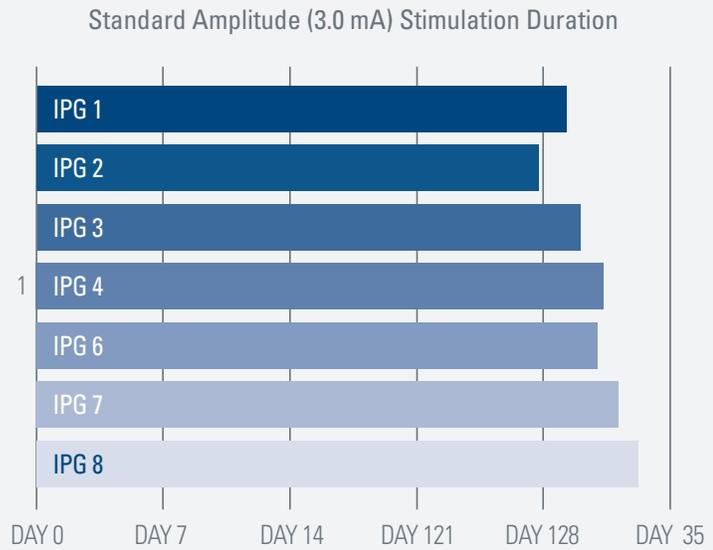
N = 7  
Amplitude: **6.0** milliamps  
Pulse Width: 60 µs  
Frequency: 130 Hz

### Low-Amplitude Treatment Parameters

N = 4  
Amplitude: **1.5** milliamps  
Pulse Width: 60 µs  
Frequency: 130 Hz

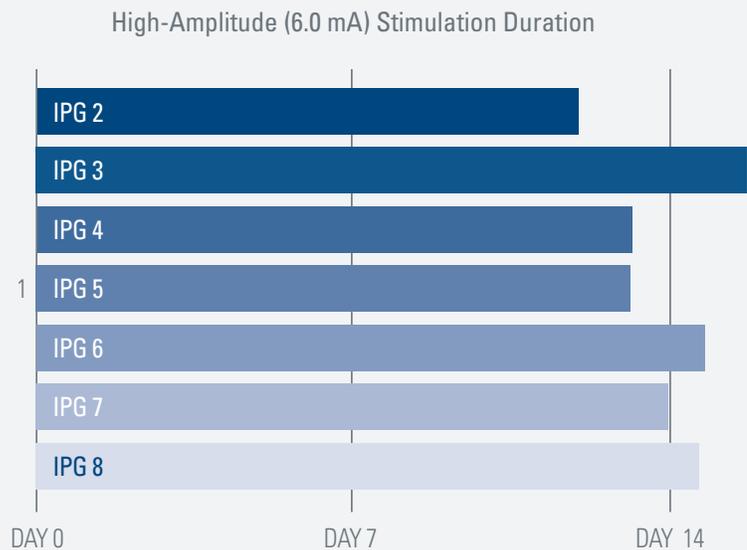
# RESULTS

Standard Settings (3.0 mA)  
Average Stimulation Time: 30 days 16 hours  
Minimum Stimulation Time: 27 days 16 hours  
Maximum Stimulation Time: 33 days 4 hours  
Standard Deviation: 1 Day 16 hours



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High Settings (6.0 mA)  
Average Stimulation Time: 14 days 5 hours  
Minimum Stimulation Time: 12 days  
Maximum Stimulation Time: 15 days 20 hours  
Standard Deviation: 1 day 8 hours

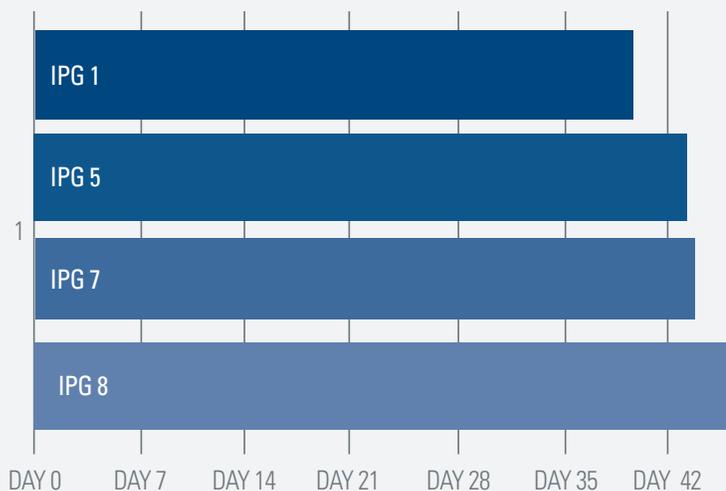


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### Low-Amplitude (1.5 mA) Stimulation Duration

#### Low Settings (1.5 mA)

Average Stimulation Time: 43 days 1 hour  
Minimum Stimulation Time: 39 days 8 hours  
Maximum Stimulation Time: 46 days 4 hours  
Standard Deviation: 2 days 10 hours



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## CONCLUSIONS

- Boston Scientific Vercise™ rechargeable DBS IPGs, at typical clinical parameters, may provide up to 4 weeks of stimulation between recharging cycles
- At high amplitudes, they may provide up to 2 weeks of stimulation between charging cycles
- At low amplitudes, they may provide up to 6 weeks of stimulation between recharging cycles

Bench Test results may not necessarily be indicative of clinical performance.

Indications for Use: The Boston Scientific Deep Brain Stimulation Systems are indicated for use in bilateral stimulation of the subthalamic nucleus (STN) as an adjunctive therapy in reducing some of the symptoms of moderate to advanced levodopa-responsive Parkinson's disease (PD) that are not adequately controlled with medication.

Contraindications, warnings, precautions, side effects: The Deep Brain Stimulation Systems or any of its components, is contraindicated for: Diathermy as either a treatment for a medical condition or as part of a surgical procedure, Electroconvulsive Therapy (ECT) and Transcranial Magnetic Stimulation (TMS) as the safety of these therapies in patients implanted with the Vercise™ DBS System has not been established, patients who are unable to operate the system, patients who are poor surgical candidates or who experience unsuccessful test stimulation. Patients implanted with Boston Scientific Deep Brain Stimulation Systems without ImageReady™ MRI Technology should not be exposed to Magnetic Resonance Imaging (MRI). Patients implanted with the Vercise Gevia™ or Vercise DBS Lead-only system (before Stimulator is implanted) with ImageReady MRI Technology are Full Body MR Conditional only when exposed to the MRI environment under the specific conditions defined in ImageReady MRI Guidelines for Boston Scientific Deep Brain Stimulation Systems. Assess patients for the risks of depression and suicide. This assessment should consider both the risk of depression and suicide as well as the potential clinical benefits of DBS therapy. Monitor patients for new or worsening symptoms of depression, suicidal thoughts or behaviors, or changes in mood or impulse control and manage appropriately. Refer to the Instructions for Use provided with the Vercise DBS System or BostonScientific.com for potential adverse effects, warnings, and precautions prior to using this product.

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

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NM-719809-AA