

Characterizing Rechargeable IPG Charge Cycle Time in DBS

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INTRODUCTION

Rechargeable Deep Brain Stimulation (DBS) Implantable Pulse Generators (IPGs) have different battery capacities, which results 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.

MATERIALS & METHODS

Study Design	Standard set up consisted of a VERCISE IPG with two BSN 2201 leads attached, in a saline solution at 37°C. Measured impedance was nominally 1000 Ω. Average 1012 Ω, Min 880 Ω, Max 1499 Ω, Std Dev 101 Ω 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.
Sample size	<i>n</i> = 7 for standard amplitude settings <i>n</i> = 7 for high amplitude settings <i>n</i> = 4 for low amplitude settings
Standard Treatment Parameters	Amplitude: 3.0 milliamps Pulse Width: 60 microseconds Frequency: 130 Hertz Contacts: 1 on each of 2 Leads
High Amplitude Treatment Parameters	Amplitude: 6.0 milliamps Pulse Width: 60 microseconds Frequency: 130 Hertz Contacts: 1 on each of 2 Leads
Low Amplitude Treatment Parameters	Amplitude: 1.5 milliamps Pulse Width: 60 microseconds Frequency: 130 Hertz Contacts: 1 on each of 2 Leads

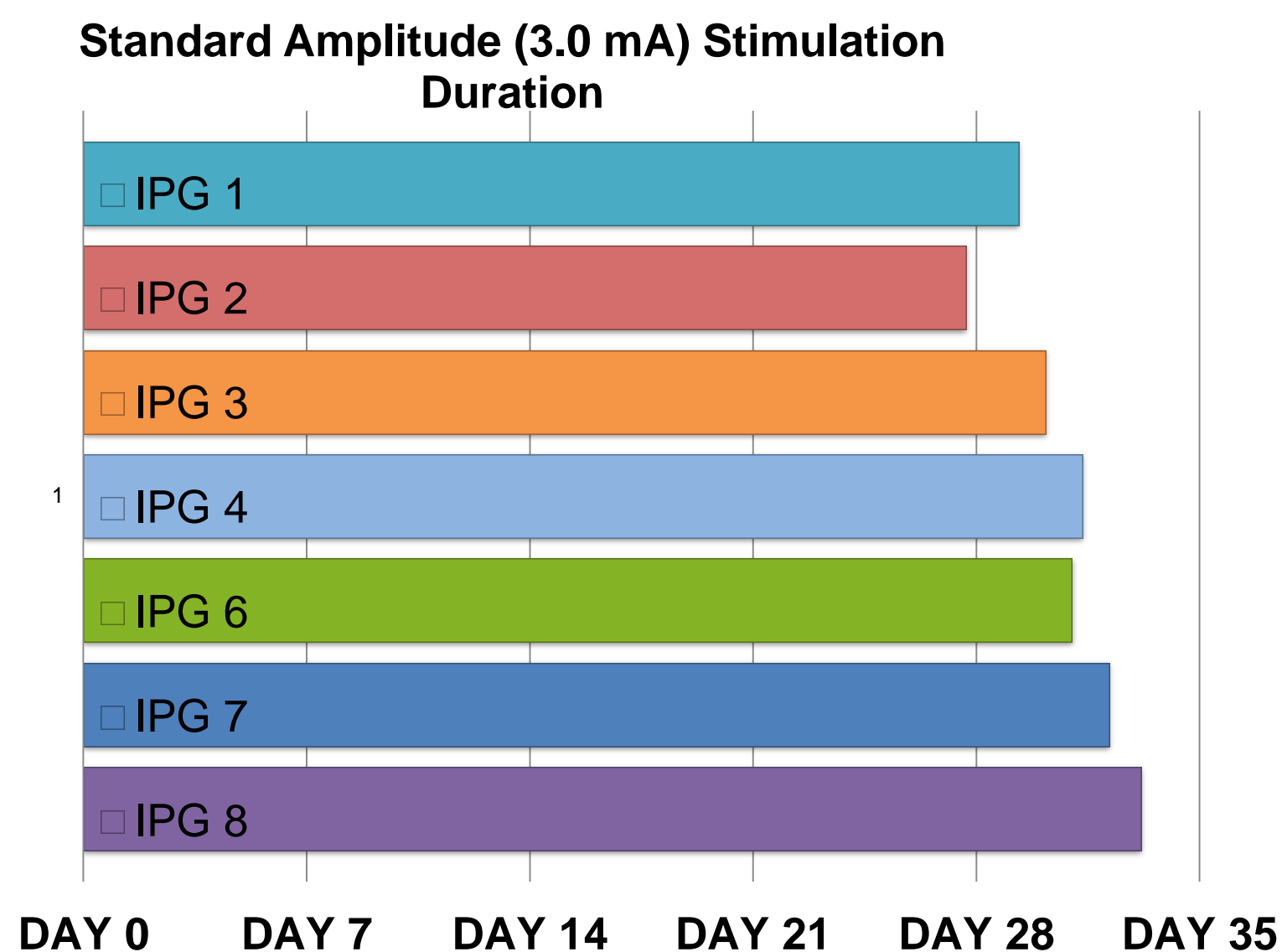
Prior to testing, each VERCISE IPG was charged, programmed, and thermally soaked overnight at 37° C. The IPGs batteries were then “topped off”, and stimulation was turned **ON**. Once turned **ON**, the test IPGs continued stimulation until they sensed critically low battery voltage and turned stimulation **OFF**. Once all IPGs were **OFF**, they were recharged and battery voltage history was collected.



RESULTS

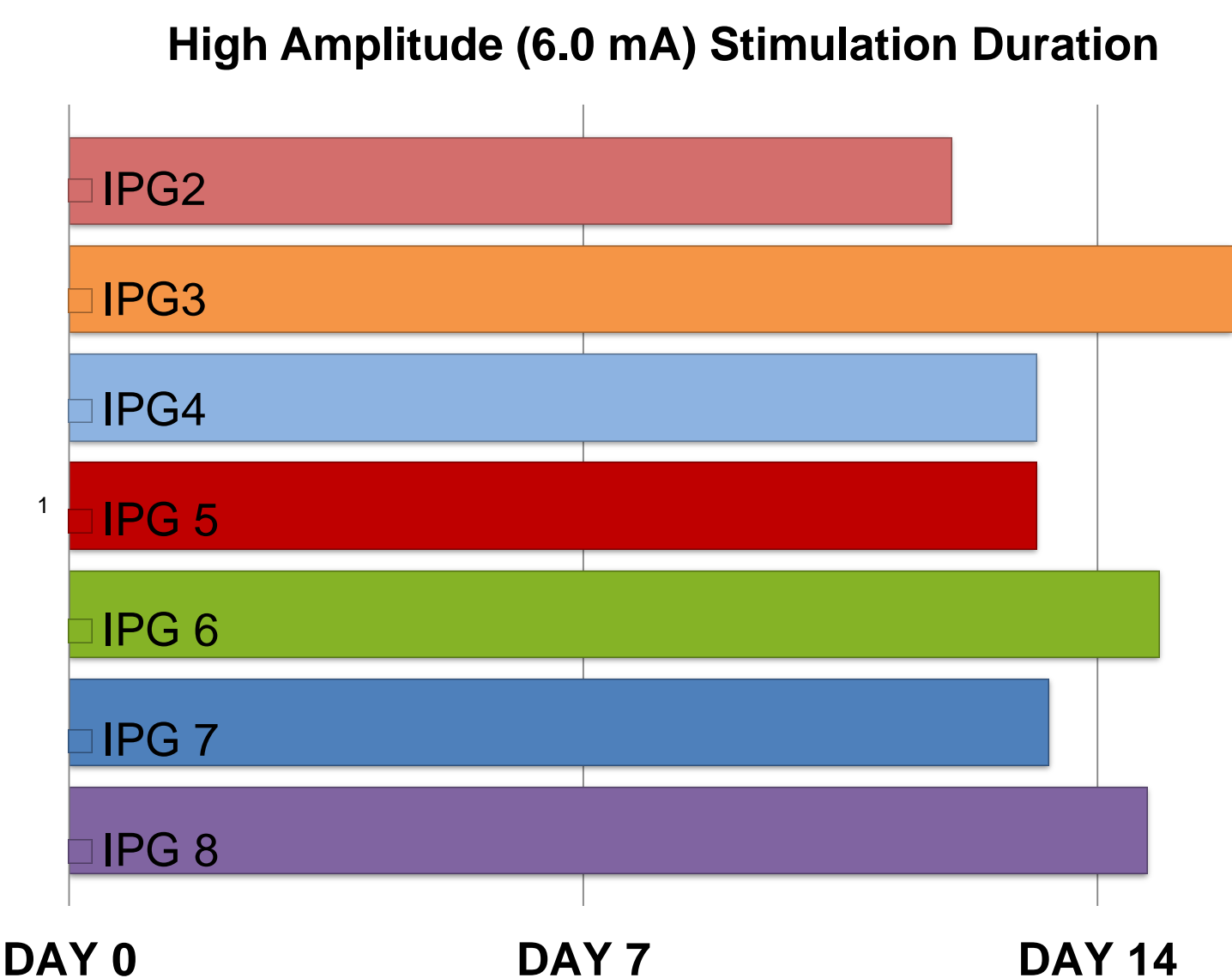
Standard Settings (3.0 mA)

Average Stimulation Time:**30 days** 16 Hour
Minimum Stimulation Time:27 days 16 hours
Maximum Stimulation Time:33 days 4 hours
Standard Deviation: 1 Days 16 hours
All VERCISE IPGs provided **27 days** of stimulation before low battery voltage forced any IPG to shut down.
All VERCISE IPGs provided stimulation for 19 days before requesting recharge.
4 IPGs provided at least 31 days of stimulation, and 1 provided 33 days of stimulation



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 days 8 hours
All VERCISE IPGs provided **12 days** of stimulation before any shut down due to low battery voltage.
Three IPGs provided more than 14 days of stimulation .

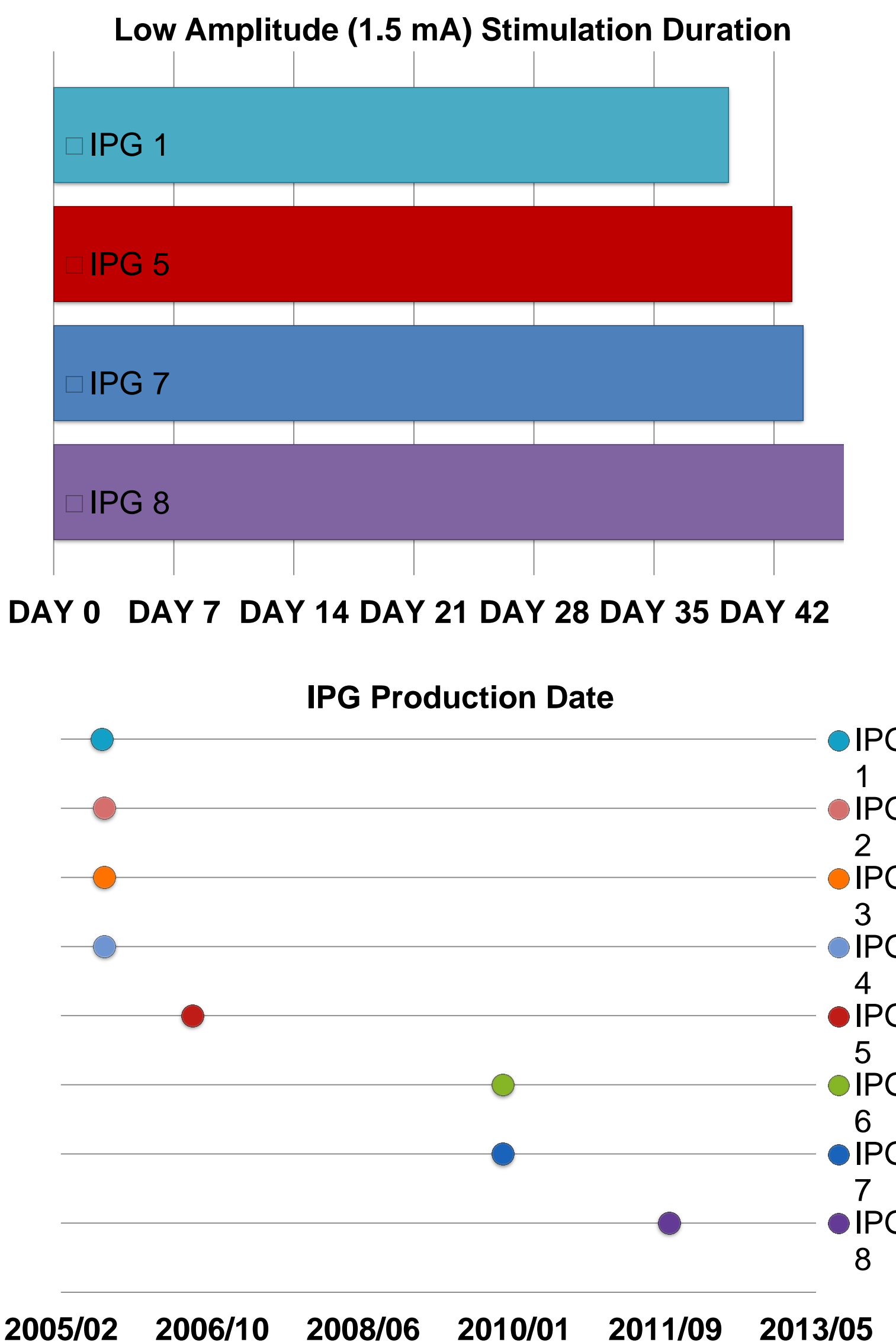


RESULTS (Continued)

Low Settings (1.5 mA)

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

All VERCISE IPGs provided **39 days** of stimulation before any shut down due to low battery voltage.
Three IPGs provided 43 or more days of stimulation .



IPG Ages

Average Age: 5.7 years
Minimum Age: 1.7 Years
Maximum Age: 7.8 Years
Std Dev: 2.5 Years

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.

The Vercise Deep Brain Stimulation System is indicated for use in unilateral or bilateral stimulation of the subthalamic nucleus (STN) or internal globus pallidus (GPi) for treatment of levodopa-responsive Parkinson's disease which is not adequately controlled with medication. The Vercise™ Deep Brain Stimulation System is indicated for use in unilateral or bilateral stimulation of internal globus pallidus (GPi) or the subthalamic nucleus (STN) for treatment of intractable primary and secondary dystonia, for persons 7 years of age and older.

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