Prodigy™ SCS System



The Prodigy MRI[™] Implantable Pulse Generator (IPG) is a rechargeable MR Conditional^{**} device featuring both BurstDR[™] stimulation and tonic stimulation modes, providing more patients with the opportunity for maximum therapy effectiveness. Now patients who may require access to an MRI scan^{**} can also access the benefits of BurstDR stimulation—a proven, patient preferred option to manage chronic pain.^{1,6}

BURSTDR STIMULATION: A PROVEN TECHNOLOGY

Supported by a body of clinical evidence, BurstDR stimulation has been proven to deliver superior pain relief over tonic stimulation.^{1,6} It works by emulating natural firing patterns in the brain⁷ and is believed to modulate both the sensory and emotional pathways—giving patients relief from both their pain sensation and the suffering^{***} associated with the pain.^{1,6,7}

SMALLEST DEVICE

The Prodigy MRI IPG is the smallest rechargeable IPG available.¹⁻⁵ Smaller devices may reduce wound closure time and improve cosmesis in patients.

LONG BATTERY LIFE

The device features the longest projected battery life,¹⁻⁵ which includes 10 years of practical recharging.¹

UPGRADEABLE THERAPY

The Prodigy MRI IPG allows for upgradable technology innovations upon approval without the need for surgical revision. The Prodigy MRI IPG is MR Conditional for Head and Extremity scans. For scan details of our current neuromodulation devices, refer to the <u>resources for radiology professionals</u>.

MOVE MORE PATIENTS FROM PAIN TO RELIEF

The Prodigy MRI[™] IPG is part of our spinal cord stimulation (SCS) portfolio. Our vision is to transform the management of chronic pain by offering advanced technologies

designed to improve patient outcomes and experience to bring the benefits of SCS to more patients. Read more about the <u>portfolio</u> and our approach to <u>chronic pain</u> <u>management</u>.

| Table 1. | IPG s | pecifications |
|----------|-------|---------------|
|----------|-------|---------------|

| Model | 3772 | 3799 | |
|---------------------|----------------------|----------|------|
| MRI status | MR conditional | Untested |]/ 🛍 |
| Height | 4.8 cm (1.89 in) | | |
| Length | 5.3 cm (2.09 in) | | |
| Thickness | 0.95 to 1.1 cm (| | |
| Weight | 29.0 g (1.0 oz) | | |
| Volume | 17.7 cm ³ | | |
| Power source | Rechargeable | | |
| Storage temperature | -10°C–55°C (| | |
| Storage humidity | 10%–90% (no | | |
| Storage pressure | 70–150 kPa (3 | | |
| Connector strength | Exceeds EN4550 | | |

| Parameter | Tonic Range | Tonic Steps | Burst Range* | Burst Steps* |
|-------------------------|-------------------------|--|--------------|--------------|
| Pulse width | 50–500 µs | Alternating 12 and 13 μs (starting with 12 μs) | 50–1000 µs | 50 µs |
| Frequency | 2–200 Hz | 2 Hz | | |
| | 200–500 Hz | 10 Hz | _ | |
| | 500–1200 Hz | 20 Hz | | |
| Burst rate frequency | — | — | 10–60 Hz | 10 Hz |
| Intraburst | _ | _ | 250–500 Hz | 10 Hz |
| frequency | | | 500–1000 Hz | 20 Hz |
| Amplitude | 0–25.5 mA (max 12 V) | 0.1–1.0 mA | 0–12.75 mA | 0.05–0.50 mA |

NOTE: Columns with * represent operating parameters for BurstDR[™] stimulation programs on IPGs capable of BurstDR stimulation mode.

NOTE: The number of stim sets in use for a tonic program governs the maximum frequency (1200/number of stim sets).

NOTE: The maximum current depends on the impedance, frequency, and pulse width settings.

REFERENCES

*BurstDR[™] stimulation, patented technology exclusively from St. Jude Medical, is also referred to as Burst stimulation in clinical literature.

**Within approved scan parameters. Refer to the Instructions for Use for full details of the St. Jude Medical[™] Prodigy MRI[™] IPG MR Conditional scan parameters.

***Pain and suffering as measured by VAS.

1. St. Jude Medical. (2016). St. Jude Medical[™] Prodigy[™] Neurostimulation System Programming and Reference Manual. Plano, TX.

2. Medtronic. (2011). RestoreSensor[™] Multi-program Rechargeable Neurostimulator Implant Manual. Minneapolis, MN.

3. Boston Scientific. (2011). Precision™ Spinal Cord Stimulation System Clinician Manual. Valencia, CA.

4. Nevro Corporation. (2012). Nevro Physician Implant Manual 10186-Eng Rev. F. Menlo Park, CA.

5. Nuvectra. (2014). Algovita[™], Spinal Cord Stimulation Patient System Manual. Plano. TX.

6. St. Jude Medical. (2016). St. Jude Medical™ Proclaim™ Neurostimulation System Clinician's Manual. Plano, TX.

7. De Ridder, D., Vanneste, S., Plazier, M., & Vancamp, T. (2015). Mimicking the brain: Evaluation of St. Jude Medical's Prodigy Chronic Pain System with Burst Technology. *Expert Review of Medical Devices*, *12*(2), 143–150. <u>http://dx.doi.org/10.1586/17434440.2015.985652</u>