NOTE: All systems and products should be considered as investigational-use only in the context of the NIH BRAIN Initiative.

PRECISION SPECTRA™ SPINAL CORD STIMULATOR SYSTEM

Description: 32-channel rechargeable implantable pulse generator. Each of the 32 current-controlled electrode contacts of the pulse generator can be programmed independently as an anode or a cathode and assigned -100% to +100% (1% step size) of the total current. This unique feature is designed to allow for precise control of the stimulation field and provide stability of the field over time. The size is 21.2 cc including the header.

Specifications:

Parameter	Range
Amplitude	0-25.5mA
Rate	2-1200Hz[a]
Pulse Width	20-1000µs[b]
Cycle ON	0s-90min
Cycle OFF	0s-90min
Ramp Up	1-10s or OFF
Programmable Contacts	32 + IPG case (Anode/Cathode / OFF)
Independent Areas of Stimulation per Program	4
Available Programs	16

a) Only one Area is available if the rate is >130pps
b) Amplitude x Width ≤12.7uC for all leads other than the 4x8 Surgical lead; Amplitude X Width≤9.1uC for the 4x8 Surgical Lead

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PRECISION WAVEWRITER™ SPINAL CORD STIMULATOR SYSTEM

Description: Latest generation 32-channel rechargeable implantable pulse generator (IPG). Each of the 32 current-controlled electrode contacts of the pulse generator can be programmed independently as an anode or a cathode and assigned -100% to +100% (1% step size) of the total current. This unique feature is designed to allow for precise control of the stimulation field and provide stability of the field over time. The IPG size is 21.2 cc including the header. Various features allow unique electrode configuration and timing stimulation patterns. For example:

- Up to 4 areas activated simultaneously with different electrode configurations and independent stimulation parameters.
- Up to 16 independent programs
- Up to 4 schedules combining up to 12 programs in sequences with resolution from seconds to days per program.
- MicroBurst3D: a burst waveform with increased resolution in the 0 to 1 second range, within and between packets of stimulation.
- Unique fields to selectively activate dorsal column or dorsal horn neural elements.

Programmable Parameters

Parameter	Range
Amplitude	0-25.5mA
Rate	2-1200Hz[a]
Pulse Width	20-1000µs[b]
Cycle ON	0s-90min
Cycle OFF	0s-90min
Ramp UP	1-10s or OFF
Programmable Contacts	32 + IPG Case (Anode/Cathode/OFF)
Independent Areas of Stimulation per Program	4
Available Programs	16
Available Schedules	4
Available Programmable Tabs per Schedule	12
Program or Wait Period Duration within a Schedule	10 secs – 7 days

a) Stimulation frequencies displayed are representative of only a single area being used in stimulation. When more than one area is used, the frequency of stimulation in an area may vary to accommodate pulses in other areas and may be less than the displayed frequency on the Clinician Programmer.

b) Amplitude x Width ≤12.7uC for all leads other than the 4x8 Surgical lead; Amplitude X Width ≤ 9.1uC for the 4x8 surgical lead.

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PRECISION NOVI™ SPINAL CORD STIMULATOR SYSTEM

Description:16 channels of multiple independent current control utilizing a primary cell battery and a different form factor (33cc including the header).

Specifications:

Parameter	Range
Amplitude	0-25.5mA
Rate	2-1200Hz[a]
Pulse Width	20-1000µs[b]
Cycle ON	0s-90min
Cycle OFF	0s-90min
Ramp Up	1-10s or OFF
Programmable Contacts	16 + IPG case (Anode/Cathode/Off)
Independent Areas of Stimulation per Program	4
Available Programs	16

a) Only one Area is available if the rate is >130pps

b) Amplitude x Width ≤12.7uC for all leads other than the 4x8 Surgical lead; Amplitude X Width<9.1uC for the 4x8 Surgical Lead

PRECISION™ MONTAGE™ MRI SPINAL CORD STIMULATOR SYSTEM

Description: Similar to Precision NOVI specifications but with additional MRI capabilities.