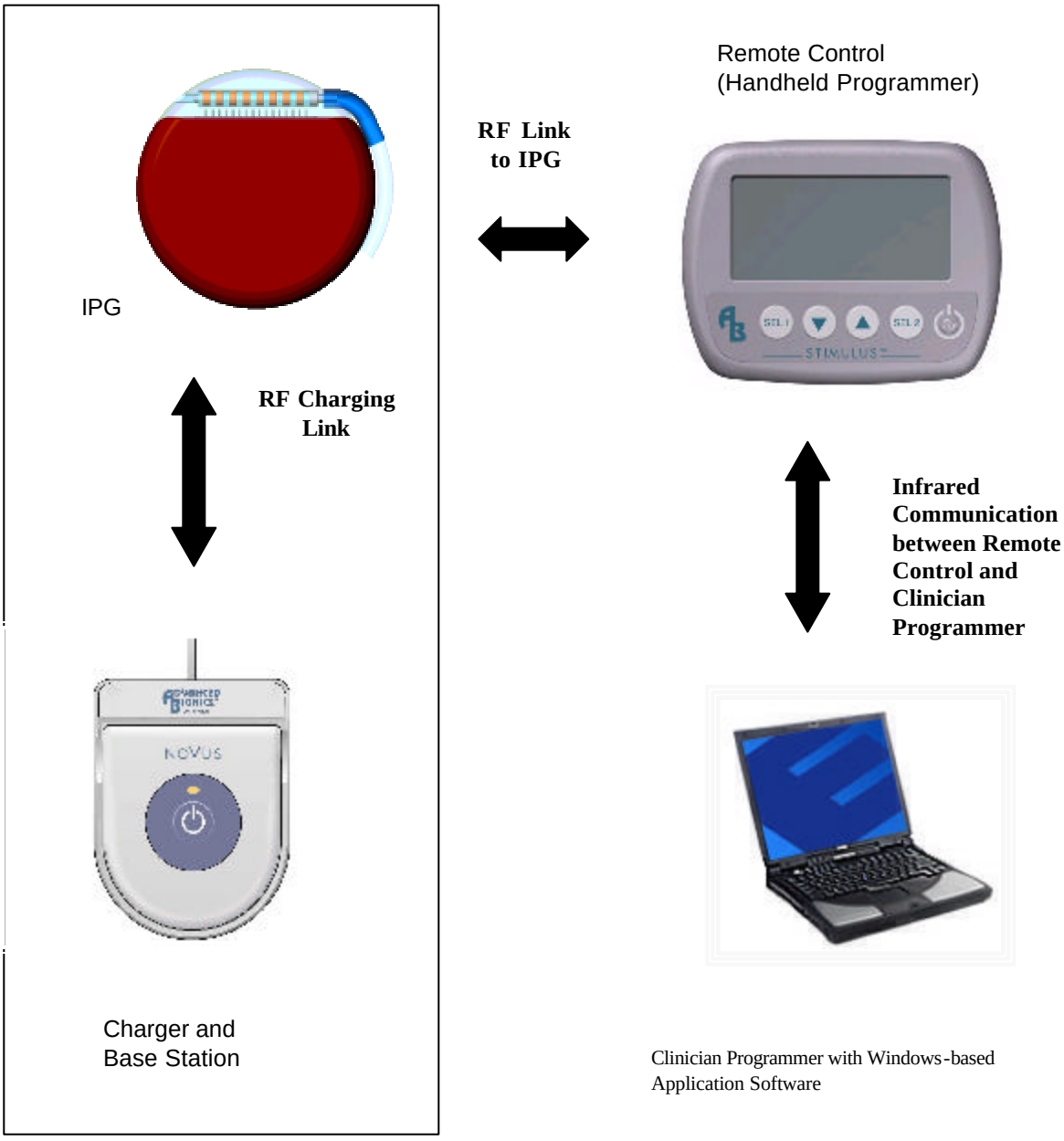
The SCS system is divided into Surgical, Clinician, and Patient Equipment. Patient Equipment includes all equipment the patient needs to have a workable system. Surgical equipment permits successful and verifiable implantation. Clinician equipment is primarily the programming system that enables stimulus parameters and patient databases to be recorded. In the block diagram below, please note that the PRECISION™ System was formerly referred to as Stimulus™ and Novus.



This submission covers the IPG and Charger, shown in the box above. The description and features of each component follows.

Charging Station (CHR)

Description: The charging station is comprised of two parts. The IPG recharger uses magnetic coupling to restore the capacity of the implanted battery and is powered by a lithium ion cell. The recharger is a base unit that allows the lithium ion cell of the charger to regain its capacity after operation and is powered via a standard wall outlet.

Features: 1) Allows full recharging of the IPG battery in a time less than 2 hours, 2) Has a user interface to indicate that charging is successfully operating, and 3) Can be recharged from any outlet using the base recharger station.

Implantable Pulse Generator (IPG)

Description: Low power design housed in a Titanium 6-4 case that communicates with the Hand held Programmer via a telemetry link. Contains the necessary electronics to decode commands and provide stimulus to 16 electrodes in groups of up to four channels.

Features: 1) Uses a rechargeable Lithium Ion battery as the main power source, 2) Provides user control over stimulus parameters, and 3) Provides safety circuits and back telemetry communication.

Hybrid Module

Contains all of the electronics with the necessary interfaces. Carries the microprocessor, the digital sequencer, the Analog Integrated Circuit, all discrete components for the RF interface, battery charger and monitor circuits and lithium ion battery. Also includes custom capacitor array containing 16 output de-coupling capacitors.

Microprocessor Module (MPIC)

This IC has an 8086 core, 16KB SRAM, two synchronous serial interfaces, a serial EEPROM interface and ROM boot loader, an efficient clock oscillator circuit and a mixer and modulator/demodulator implementing the QFAST RF telemetry method supporting bi-directional telemetry at 8kbits/second. The processor also includes the necessary interfaces to communicate with the other individual ASICs.

Analog ASIC Module (AIC)

The main custom integrated circuit that provides power regulation, stimulus output, impedance measurement and monitoring.

Digital ASIC Module (DigIC)

The digital integrated circuit (DigIC) is the primary interface between the processor and the AIC output circuits. The main function is to provide stimulus information to the output current generator register banks.

RF Module

Antennas and preamplifiers that receive signals from the HHP and provide interface at adequate levels for the demodulation/modulation of the communication frames in the

microprocessor. Transmit and receiver carrier frequency of 125 kHz. The antenna consists of a ferrite rod located in the epoxy header of the IPG. The antenna makes connection to the implant hybrid via two of the header feedthrough pins. Capacitors DC isolate the antenna from the hybrid circuit

Battery Charger/Protection Module
Provides battery charging and protection functions.

AC-DC Transformer
The AC-DC transformer converts the AC mains input (100-240 VAC) and outputs 5 VDC to the charger base station. The transformer is an off-the-shelf component.

Charger Base Station
The charger base station provides power to the charger. Its primary purpose is to serve as a base for the charger when not in use.

Charge Controller
The charge controller is an off-the-shelf, linear regulation battery charger IC, Linear Technology LTC1731-4.2.

Battery Protection
The battery protection module prevents the battery from potentially hazardous operating conditions such as overvoltage, undervoltage, and overcurrent. A battery protection IC (Motorola MC33349N-7R1) detects if any of the voltage or current limits are exceeded, and will disconnect one of two FETs in series with the battery to interrupt the fault. A PTC fuse (Raychem miniSMDC110) provides additional overcurrent protection.

Transmitter Coil
The transmitter coil is a 43 turn, double layer, 24 AWG copper Litz wire (16 strands of 36 AWG wire) air-core coil, and has a typical inductance of 100 µH and a DC resistance of 0.55 ohms. The coil is tuned for resonance at 80 kHz with a parallel capacitor.

RF Amplifier
The RF amplifier module transmits the power from the charger battery to the IPG battery. It consists of a high-efficiency Class E power amplifier driving a resonant coil for electromagnetic coupling to the receiver coil in the implant. The coil is driven at 80 kHz, with a maximum output power of 3 W.

Alignment Indicator
The alignment indicator module indicates if the charger and implant are in proper alignment for optimum charging. A tone will sound if alignment is not achieved; once in alignment, the tone is disabled.

Charge Complete Indicator
The Charge Completion Indicator module indicates if either the IPG battery has completed charging or if the charger battery is depleted.