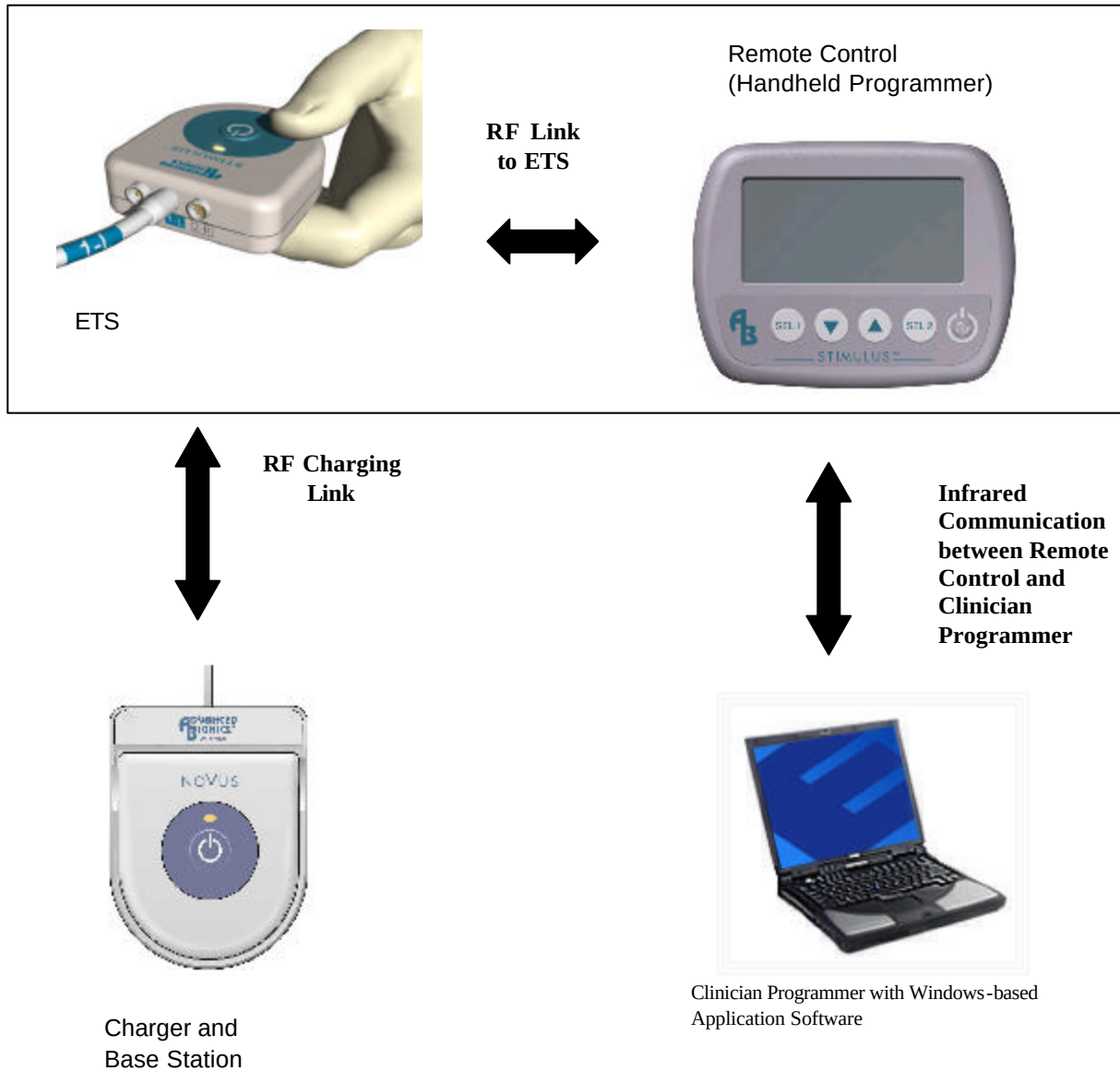


The SCS system is divided into Surgical, Clinician, and Patient Equipment. Patient Equipment includes all equipment the patient needs to have a workable system. Surgical equipment permits successful and verifiable implantation. Clinician equipment is primarily the programming system that enables stimulus 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 ETS and Handheld Programmer, shown in the box above. The description and features of each component follows.

External Trial Stimulator (ETS)

Description: The External Trial Stimulator is an externally worn pulse generator that is used for 7 to 10 days for evaluation purposes before the implantation of the IPG.

The ETS is applied with an adhesive patch to the skin of the patient, or by a belt clip or other form of convenient carrying pouch.

Features: 1) Device used in OR to test the electrode array during placement, 2) Full bi-directional communication to the Clinician's Programming System, and 3) Allows the patient or clinician to evaluate the stimulus levels.

Hand Held Programmer (HHP)

Description: Programmer that may be used by the patient or clinician to change the stimulus parameters of the IPG or ETS via a telemetry link.

Features: 1) Small programmer with easy to read LCD screen, 2) Software for ease of programming and user interface, and 3) Powered by field replaceable primary battery.