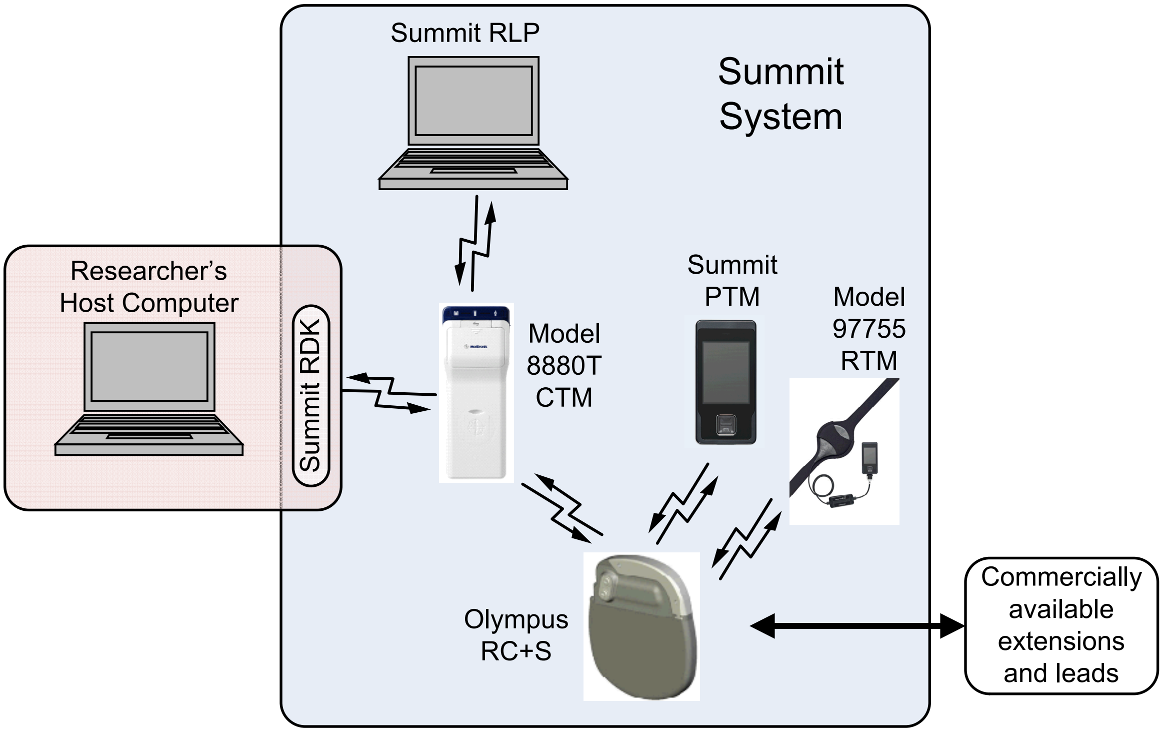

Figure 1

The purpose of the Brain Modulation sensing research platform [Summit system] is to enable clinicians with the interest and ability to probe brain neural networks the capability to explore potential biomarkers, prototype closed-loop algorithms, and develop new insights into disease areas. The core user segments for this system are research-oriented clinicians and biomedical engineers. This research platform is intended for limited availability; not as a commercially available device, but as a research tool with capabilities to serve investigational purposes.

This system is designed to explore therapy enhancements including, but not limited to, reducing overall therapy power drain to enable longer device life or smaller device size, improving therapy outcomes to drive greater patient adoption of DBS therapy, reducing side-effects of stimulation, and informing optimal programming settings and targeting of DBS leads to improve the efficiency and application of DBS therapy by clinicians.

The sensing feature is based on the hypothesis that LFPs and evoked potentials can be measured in Neurological disorders. Preliminary use of Activa PC+S in physician sponsored clinical studies reinforce this notion. Some of the key LFP findings and publications are:

- "Beta Oscillations in Freely Moving Parkinson's Subjects Are Attenuated During Deep Brain Stimulation" Quinn et. Al. Movement Disorders, Vol. 00, No. 00, 2015
- "Deep Brain Recordings Using an Implanted Pulse Generator in Parkinson's Disease" Neumann et. Al. Neuromodulation 2015

The Summit System is designed to take the next step from measuring LFP activity to providing algorithms based on LFP activity. Literature demonstrating that this is possible includes the following:

- "Adaptive Deep Brain Stimulation in a Freely Moving Parkinsonian Patient" Manuela Rosa et. Al Movement Disorders, Vol. 00, No. 00, 2015
- "Adaptive deep brain stimulation in Parkinson's disease" Beudel et. Al. Parkinsonism and Related Disorders 22 (2016) S123eS126

Details of the Bidirectional Investigational Research Tool (Olympus RC+S)

As shown in **Figure 2**, a complete investigational research tool is being developed leveraging an existing system in development for commercial use. This system provides sensing, stimulation, power management, real-time telemetry, and accelerometer access in an implant. The hardware system links with a distributed algorithm interface, which serves as the data science portal for 24/7 event storage and on-line algorithm implementation.

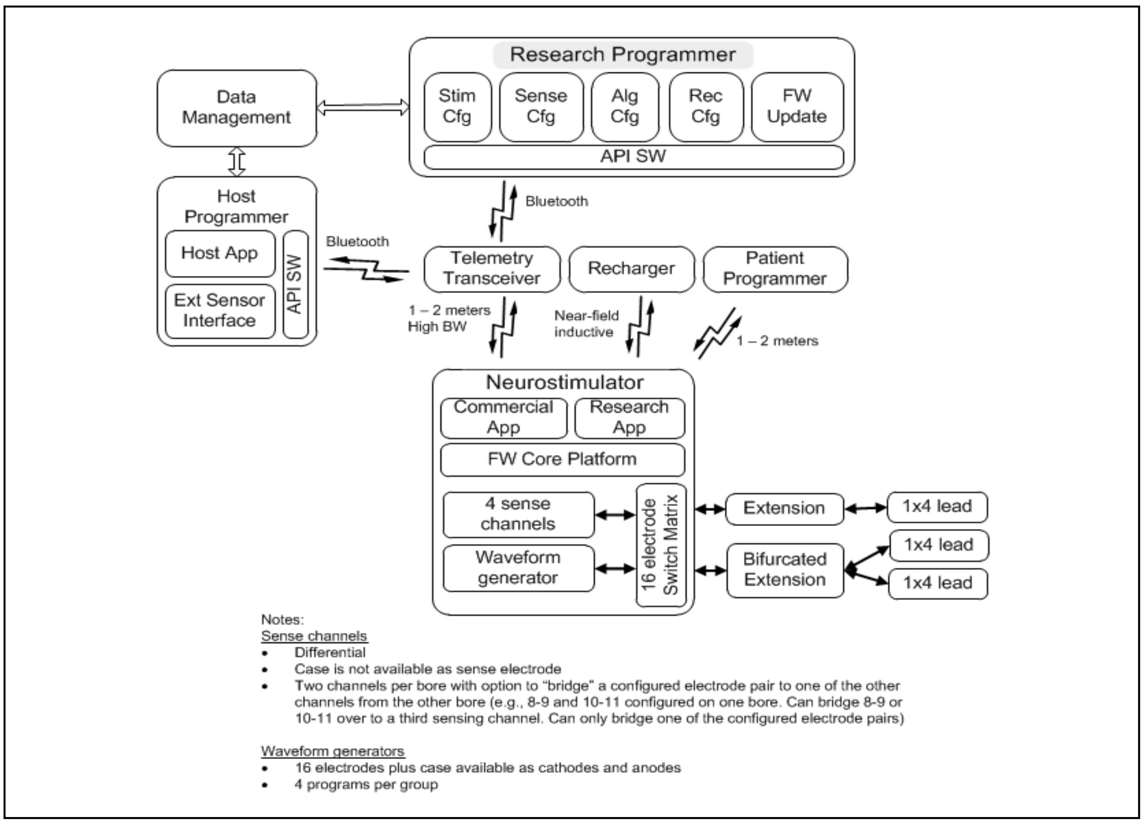

Figure 2: System architecture for the bi-directional neural interface system.

- **Sensing Circuits**

The system consists of a custom integrated circuit with chopper-stabilization to enable sub-microvolt resolution to neural signals down to the sub-Hz frequencies, while maintaining sufficient input impedance to interface to common neuromodulation electrodes. A multiplexing front-end allows a sampling of up to 4 simultaneous dipoles from the electrode network.

- **Stimulation Circuits**

The architecture allows for multiple degrees of freedom in space, patterns and time for modulating the network. The baseline stimulation capabilities support standard DBS therapies. Each electrode interfaces with an independent stimulation circuit capable of driving multiple patterns. Multiple electrodes will be accessed simultaneously through their respective stimulation circuits to shape the volume of tissue that is activated.

- **Capability for Sensing-during-Stimulation**

The central processing unit (CPU) managed coordinated action of the custom stimulation and sensing circuits, in combination with a proprietary front-end circuit, will allow for resolving neural field potentials in the presence of stimulation (TNSRE 2012) and maintenance of the resolution floor in the physiological range of interest.

- **Module Control and Integration**

The implanted device is controlled through telemetry to an outside research programmer, as detailed in **Figure 1**. An interface API allows for simplified communication between the investigational implant sub-system and the external brain computer interface (BCI) environment.

- **Physical size**

The implantable neurostimulator (INS) is designed for pectoral placement consistent with existing implant experience; Figure 1.

- **Lead Compatibility**

The system uses the same leads as the Activa RC/PC system (Model 3387, 3389, 3391, and Resume-based electrode systems for investigational use) and the extension is equivalent to the Model 37085 extension, in 40 and 60 cm lengths, however it now has a Y-connector that allows for up to four independent electrodes with four contacts each to be routed into the Olympus RC+S.

- **Recharging Capability**

As a rechargeable system, the RC+S allows increased use of telemetry while the device is being used for research purposes. This functionality enables data streaming without minimal impact to device longevity. Additionally, the device includes distance telemetry, which frees the patient to continue with the activities of daily living during algorithm assessment. The Olympus RC+S can stream continuously for more than 30 hours between recharges.

Data sciences and algorithm support

- **Data Streaming**

A bi-directional RF link using the Medical Information Communication (MICS) band enables data to be streamed from the rechargeable device to the research platform or up to the cloud. The latency of the between the research platform and the device is approximately 100ms round-trip (~50mS in either link direction).

- **Algorithm Implementation**

An application-programming-interface (API) is available on the research platform to allow for efficient access to the electronics module through a variety of software programs. This will enable rapid data analysis and algorithm prototyping. Embedded algorithm support includes a microprocessor sub-system supported with dedicated hardware subroutines for spectral analysis, median calculation and automated loop recording.

- **Data Gathering and Loop Recording**

The device includes the ability to acutely store data for later download (in case streaming is not activated). The loop recorder can be set to continuously buffer data to allow for an “event” trigger to sample data for several minutes prior to the event as well as post-event. Events can be set by internal clock timers, algorithm-classifier triggers, or patient activation through their handheld telemetry module. **Table 1** provides a summary of key specifications.

Specification	Value
Implant recharge interval	> 30 hrs.; continuous telemetry
Secure distance telemetry from Medtronic RC+S to External telemetry	Encrypted, >100kbps, >1m Latency <100ms roundtrip (<50ms uplink)
Local control and algorithm processing	spectral processor, fast-Fourier transform, phase detection
Streaming data capability	4 channels real-time
Embedded sensors (noise floor, processing, sense and stimulation performance)	Maintain noise floor with or without stimulation
API interface	Bluetooth (Secured) or USB to host system
Maintenance of existing therapy capability	Minimum capability of predicate Activa® therapy; including full impedance checks on all electrodes for chronic verification of suitable tissue electrode interfacing

Table 1

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