1.0 Purpose

The purpose of this document is to provide product specifications for applicable Hornet Lead Package

2.0 Scope

In scope for this document are the product specifications inclusive to the Hornet IPG and charger; as part of the CARSS program Nest 3. The CARSS program stands for Center for Autonomic Nerve Recording and Stimulation Systems. The CARSS is part of the NIH Human Open Research Neural Engineering Technologies (HORNET) initiative for open-architecture, open-source implantable neuromodulation system. This includes a collaborative team between University of Southern California (USC, Los Angeles, CA), Medipace Inc (Pasedena, CA), and Med-Ally, LLC (Goose Creek, SC). The purpose of the system which the IPG and charger is a portion of is to enable community-supported neurotechnology platform to remove technical and financial hurdles to getting access to implantable neuromodulation technologies. Nest 3 focuses on a set of 5 standard leads: SNS, PDMS cuff, ECG, EMG, and AMS lead.

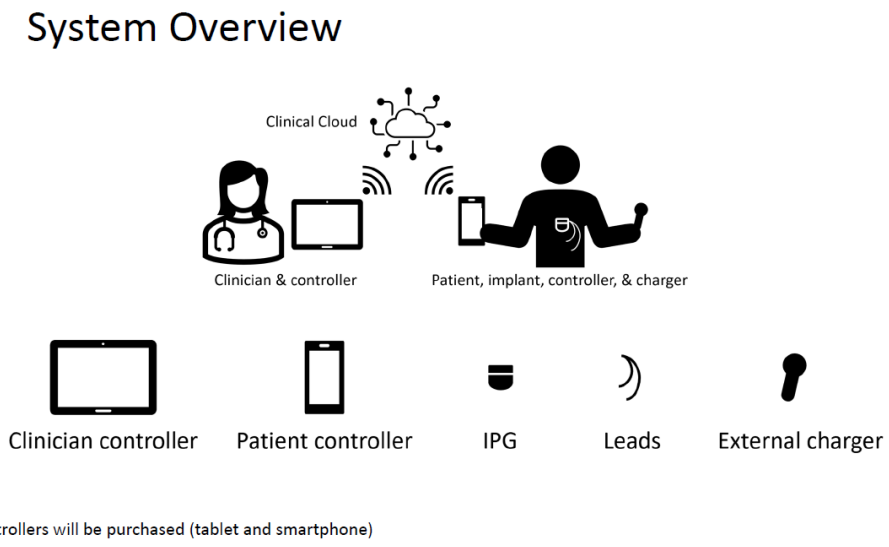
3.0 Definitions

Abbreviation	Definition
BLE	Bluetooth Low Energy. Operates on frequencies: 2.400 GHz – 2.4835 GHz
Controller	A computing device capable of running the NBS-EPG and IPG Controller application(s) tailored for physicians, the patient, or researchers.
IPG	Implantable Pulse Generator
HW	Hardware
SW	Software
PCB	Printed Circuit Board
PSD	Product Specifications Document
GUI	Graphical User Interface

Abbreviation	Definition
HIPAA	Health Insurance Portability and Accountability Act of 1996. U.S. legislation that provides data privacy and security for safeguarding medical information.
Wi-Fi	A facility allowing an electronic device to wirelessly transfer data or connect to the Internet using IEEE 802.11 standards. Operates on frequencies: 900 MHz, 2.4 GHz, 4.9 GHz, 5 GHz, 5.9 GHz and 60 GHz.
NIH	National Institute for Health
CARRS	Center for Autonomic Nerve Recording and Stimulation Systems
Hornet	Human Open Research Neural Engineering Technologies
Nest	Major component or module of the CARRS system

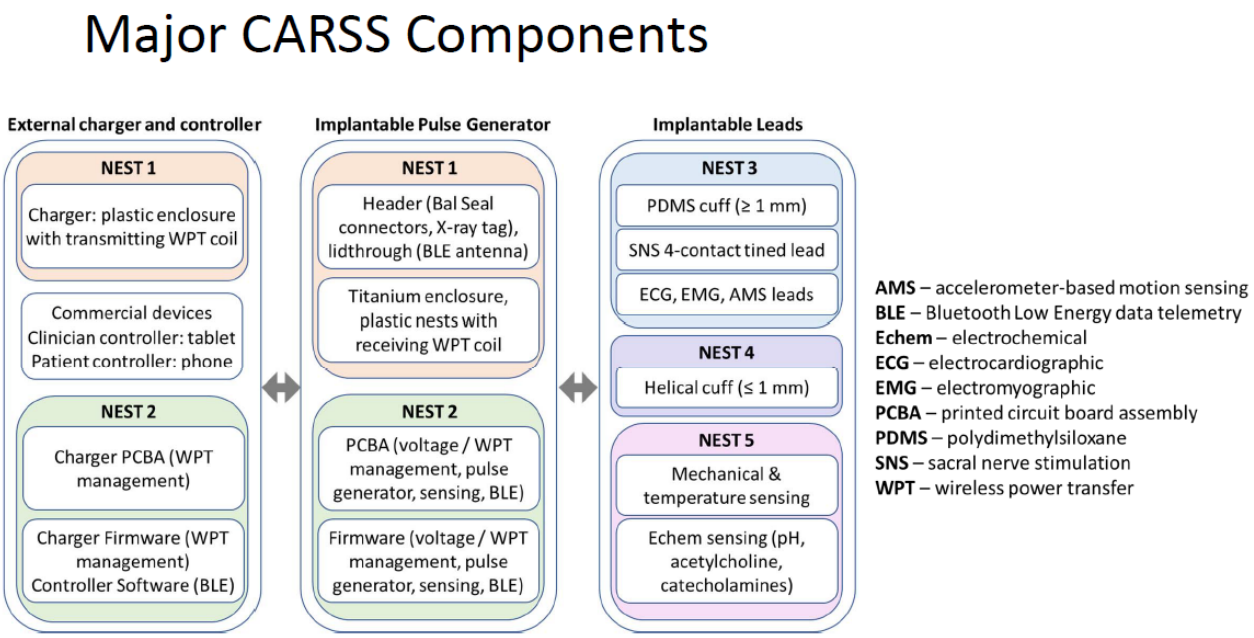
4.0 General Description of Product

The CARRS system is an open source system to enable developments in stimulation and sensing technologies. The system is capable of closed loop stimulation and sensing or can be used independently. The system components are: external charger and controller, implantable pulse generator, collection of interoperable and implantable leads.



Each portion of the CARSS system has been split into major components called nests. See

figure below for details of major components or modules of the CARRS system:



This document will only address Nest 1.

The IPG and charger for the CARRS system will be designed with the following engineering design principles as applicable:

- Material and component selection for maximizing the performance.
- Long-term reliability, redundancy, and fail-safe operations.
- Modularity, plug-and-play operation and off-the-shelf components.
- Preference for simpler and proven solutions over more complex and higher-risk ones.

6.0 Specifications

6.1 Leads Mechanical Specifications

PRD ID	Category	Specification Text
PRD-LDS-0001	All	The leads are provided in the following lengths: 35 cm

PRD ID	Category	Specification Text
		50 cm 50 cm 70 cm
PRD-LDS-0002	All	The outside diameter of the leads shall be 1.27 mm diameter
PRD-LDS-0003	All	The SNS, PDMS cuff, EMG, ECG, and AMS lead have 2 or 4 filar coiled leads with 0.70 mm pitch or greater.
PRD-LDS-0004	All	The SNS, PDMS cuff, EMG, ECG, interconnect and AMS lead wire diameter is .102 mm/ 0.004" with 0.0127 mm/0.0005" thick coating.
PRD-LDS-0005	All	The proximal contacts have 1.5mm length contacts.
PRD-LDS-0006	All	The proximal set screw contact is 3mm in length.
PRD-LDS-0007	All	Tines and trumpet anchor for anchoring can be added for each lead as needed.
PRD-LDS-0008	All	The each connector utilizes a mechanism that holds the inserted lead in place. (e.g. set screw)
PRD-LDS-0009	All	All the materials of the Lead Kit that are in contact with the body have been selected as known biocompatible.
PRD-LDS-0010	All	The primary components for the Leads and interconnects shall be fabricated from the following materials: • Lead Body: Polyurethane, Pellethane 2363-55D • Proximal Inner Tube: PEEK • Distal Inner Tube: Polyurethane, Pellethane 2363-80A • Distal Electrodes: Platinum-Iridium (90/10) • Proximal Contacts: MP35N • Conductor Cable: PTFE coated Platinum-Iridium (80/20) • Setscrew: Titanium • Connector Block: MP35N

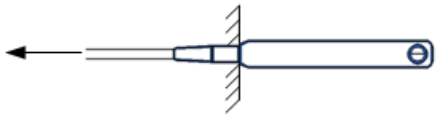
PRD ID	Category	Specification Text
		• Bal Seal connectors: MP35N and Pt-Ir • Silicone molded components Silicone Rubber - Med-4850, or similar • Connector block and set screw: 316L stainless steel • Misc Adhesives: Epoxy - Epotek 301, Silicone Rubber - Med-2000, urethane adhesive, silicone adhesive MED3-4213 • Suture: polypropylene or silk • Tines: pellethane • Suture Needle, crimp tubes: 316L Stainless Steel
PRD-SNS-0001	SNS	SNS leads have electrodes on the distal end that are 3 mm in length with 3 mm space between electrodes
PRD-SNS-0002	SNS	Up to 4 tines in series are added to the lead body to aid in lead retention and stability in vivo.
PRD-SNS-0003	SNS	The lead systems incorporates a radio-opaque marker at the distal array in the form of platinum electrodes
PRD-SNS-0004	SNS	The leads with a stylet inserted is able to pass completely through an 18-gauge needle
PRD-INT-0001	Interconnect	The distal connector of the interconnect incorporates a connector block and set screw for securing the lead to the connector
PRD-INT-0002	Interconnect	The distal connector of the interconnect accommodates two bipolar male connectors.
PRD-INT-0003	Interconnect	The proximal connector of the interconnect interfaces with a quadipolar Sygnus Neuro Bal Seal connector in the IPG header.
PRD-INT-0004	Interconnect	The interconnect connection portion is smaller than 0.5” X 1.5” X 0.5”
PRD-EMG-0001	EMG	The EMG lead incorporates a Suture style needle

PRD ID	Category	Specification Text
PRD-EMG-0002	EMG	The EMG lead incorporates a suture connecting the needle to the stimulating portions of the lead
PRD-EMG-0003	EMG	The EMG lead contains a single stimulating or sensing electrode
PRD-EMG-0004	EMG	The EMG lead contains a Tumpet anchor to anchor electrode in place
PRD-EMG-0005	EMG	The EMG lead interfaces with the bipolar connection.
PRD-EMG-0006	EMG	The insertion needle length on the EMG lead is 32 mm
PRD-ECG-0001	ECG	The ECG lead has two electrodes that can be 3mm to 100 mm apart.
PRD-ECG-0002	ECG	The ECG lead has two anchor points: one at the end of the lead and the second proximal to the first electrode
PRD-ECG-0003	ECG	The ECG lead interfaces with the bipolar connection
PRD-CUF-0001	Cuff	The cuff electrode will have an inner diameter that accommodates nerves 2.5-5.5 mm in diameter – nominally 3.58 mm nerve.
PRD-CUF-0002	Cuff	Cuff leads shall have two electrodes for bipolar stimulation.
PRD-CUF-0003	Cuff	Cuff length along the nerve is 10 mm
PRD-CUF-0004	Cuff	Lead exits cuff parallel to nerve
PRD-CUF-0005	Cuff	Cuff electrode spacing is 2.5mm
PRD-CUF-0006	Cuff	Electrodes are located 2.25mm inboard from edge of cuff
PRD-CUF-0007	Cuff	Silicone cuff thickness is 1 mm
PRD-CUF-0008	Cuff	Cuff includes dual sutures 35 mm long and 0.2mm diameter

PRD ID	Category	Specification Text
PRD-AMS-0001	AMS	The AMS lead is a quadripolar lead
PRD-AMS-0002	AMS	The AMS lead has three suture points to anchor AMS distal end

6.2 Testing Requirements

PRD ID	Specification Text
PRD-LDS-0011	The leads contacts are electrically isolated to prevent interference between signals.
PRD-LDS-0012	The Leads and Extensions shall be designed to withstand the following flexure cycles: -The Lead and Extension Connector shall withstand a minimum of 82,000 flex cycles. -The Lead and Extension body sections shall withstand a minimum of 47,000 flex cycles. Reference: EN45502-2-1 CENELEC Standard for Brady Pacemakers Testing will be performed per EN4552-2-1/ISO14708-2: 23.5.
PRD-LDS-0013	Once the lead is locked in place into the IPG port or extension with the set screw fully torqued, the retention force of the lead shall be 10 N minimum along the lead axis relative to the connector. This retention force may exceed the destructive pull force of the inserted lead. EN45501-1 section 23.6 / ISO 14708-2: 23.6
PRD-LDS-0014	When a tensile force of 5N is applied for 2 seconds along the main axis the of the lead or extension the assembly must not electrically and/or mechanically fail. ISO 14708-2: 23.3
PRD-LDS-0015	Lead Insertion/Withdrawal Force Connector: The insertion and withdrawal force of a lead connector array into the IPG port connector or lead Extension port shall not exceed 2.2 lbs (9.8 N).

PRD ID	Specification Text
PRD-LDS-0016	The interface between the extension distal connector body and a connected component shall not electrically and/or mechanically fail when tensile force of 2.2 lbf (9.8N) is applied between the components or across their interface. Deformation of components is allowable. Fracture of tubing or separation of tubing from a component is not allowable.  Examples of tensile force arrangements between an attached component and the Extension body.
PRD-LDS-0017	The resistance for each connection in the distal connector shall remain ≤1000 Ohms and must not mechanically fail when bent 45°±2° off the main axis in any direction ISO 14708-2: 6.2.3
PRD-LDS-0018	All the leads in the Leads Kit shall observe industry standard wiring practices for this type of application. The contact female connectors at the distal end and male contacts at the proximal end shall be connected through a one-to-one connection.
PRD-LDS-0019	The proximal contact arrays of the Lead shall withstand 20 insertion and withdrawal cycles into the connector on the interconnect cable without causing physical or functional damage to the Lead.
PRD-LDS-0020	The proximal contact arrays of the Lead and Extension shall withstand 20 insertion and withdrawal cycles into the port connector on the IPG without causing physical or functional damage to the Lead.
PRD-LDS-0021	The lead assemblies should be able to withstand (function after experiencing) the following:

PRD ID	Specification Text
	Accelerated aging per ISO 14708-1:19-1
PRD-LDS-0022	When the lead or Extension assembly is dry in air, the electrical leakage between conductors at 100 ± 5 Volts DC shall be ≤10 microamperes. ISO 14708-2: 16.1
PRD-LDS-0023	When the lead or Extension assembly is dry in air, the electrical leakage from any conductor to the outside lead body at 1000 ± 50 Volts DC shall be ≤0.75 microamperes per mm^2. ISO 14708-2: 16.2