## 1.0 Purpose

The purpose of this document is to provide product specifications for applicable Hornet Implantable Pulse Generator IPG and charger mechanical aspects.

## 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 1. 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 1 focuses on the IPG and charger mechanical aspects.

## 3.0 Definitions

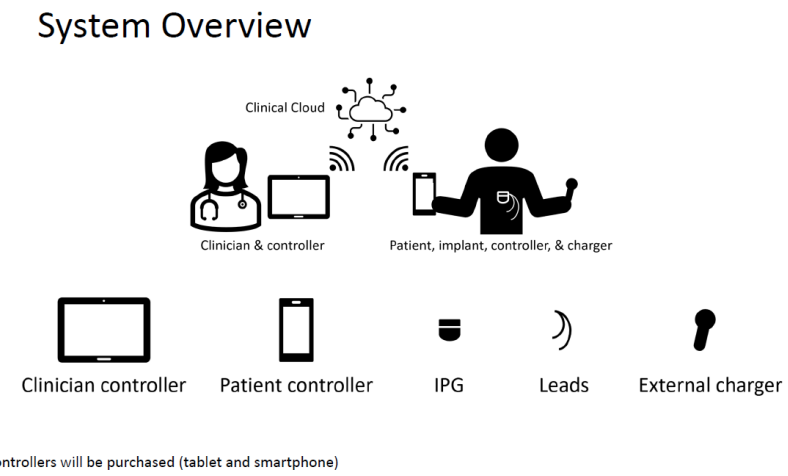
| Abbreviation | Definition |
|---|---|
| BLE | Bluetooth Low Energy. Operates on frequencies: 2.400 GHz – 2.4835 GHz |
| Controller | A computing device capable of running the NBS-EPG and IPG Controller application(s) tailored for physicians, the patient, or researchers. |
| IPG | Implantable Pulse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

| Abbreviation | Definition |
|---|---|
| Nest | Major component or module of the CARRS system |

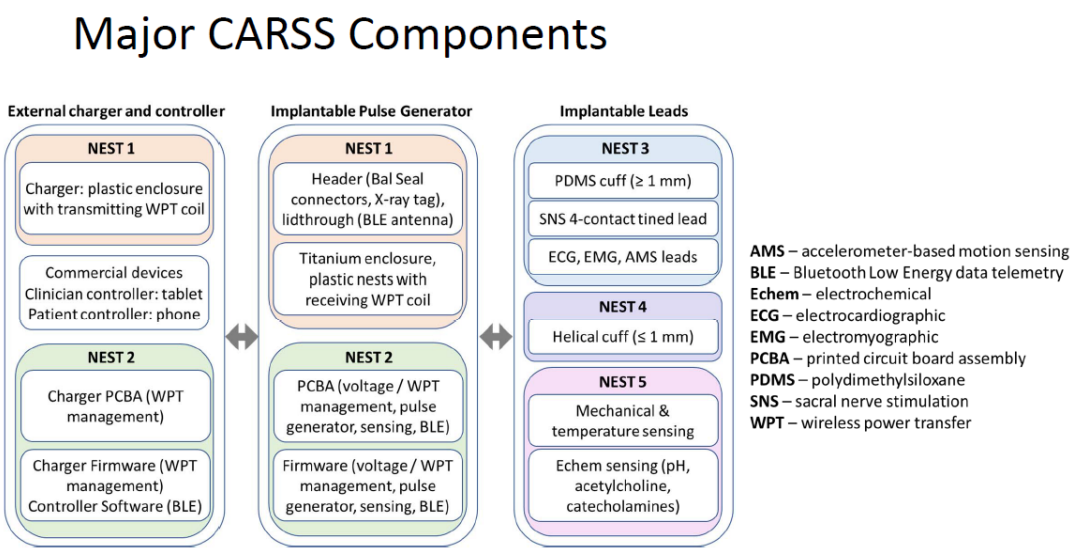
## 4.0 References

## 5.0 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 only addresses 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 Mechanical Specifications

### 6.1 IPG

| PRD ID | IPG Specification Text |
|---|---|
| PRD-IPG-0001 | The IPG incorporates 16 Lead Contacts |
| PRD-IPG-0002 | The contacts are arranged in the header in 4 sets of 4 contacts. |
| PRD-IPG-0003 | With only a small modification, the header can be arranged with one or both lead bores in an 8 contact configuration. |
| PRD-IPG-0004 | The lead connectors are Bal Seal Sygnus 2.8 mm pitch connectors with accompanying silicone seals |
| PRD-IPG-0005 | Bluetooth or WiFi antenna (2.4 GHz capable) is located in the header |
| PRD-IPG-0006 | Hermetic assembly accommodates 2 Quallion QL0200I EnerSys Batteries or similar |

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| PRD-IPG-0007 | Hermetic Assembly encloses a charge coil similar to WPT coil 760308101107, Wurth Elektronik |
| PRD-IPG-0008 | Hermetic Assembly encloses the suppled PCBA |
| PRD-IPG-0009 | A nest that supports and stabilizes the PCBA, coil, and batteries within the hermetic assembly |
| PRD-IPG-0010 | The IPG electronics assembly will be hermetically sealed in an enclosure that will be sealed to a helium leak rate no greater than $1X10^{-8}$ in accordance with the MIL STD 883K |
| PRD-IPG-0011 | The IPG shall have a header with a location to secure to the subject with a suture |
| PRD-IPG-0012 | The IPG has a connector block with set screw on each of the 4 (or in the case of an octopolar leads – 2) to mechanically lock in the lead into each lead bore. |
| PRD-IPG-0013 | A set screw is packaged with the IPG to use with the set screw. The torque wrench is 5 in-oz Hex |
| PRD-IPG-0014 | The IPG accommodates 2 EnerSys Quallion QL02001 batteries and if needed can accommodate an off the shelf primary battery greater than 0.75AHr if possible. |
| PRD-IPG-0015 | The IPG outermost dimensions are less than 2” X 2.6” X 0.5” |
| | **IPG Materials** |
| PRD-IPG-2001 | All the materials of the IPG Kit that are in contact with the body are selected for known biocompatibility. |
| PRD-IPG-2002 | The IPG case is be made of Grade 23 titanium |
| PRD-IPG-2003 | The IPG header is made of epoxy (EPOTEK 301) to enclose the header components |
| PRD-IPG-2004 | The IPG has a feedthrough consisting of, at minimum, of a titanium lid, ceramic insulation components, and Pt-Ir pins with gold braze |
| PRD-IPG-2005 | The Bal Seals are made of MP35N housing with Pt-Ir springs and incorporates Med-4850 silicone spacer |
| PRD-IPG-2006 | A connector block and set screw are made of 316L |
| | **IPG Testing** |
| PRD-IPG-3001 | The IPG electronic assembly should be able to withstand (function after experiencing) the following:<br>Shelf drop per ISO 14708-1:10.1, 23.2, 23.7, |
| PRD-IPG-3002 | The IPG electronic assembly should be able to withstand (function after experiencing) the following:<br>Vibration test at 5-500 Hz for 30 mins per ISO 14708-1:23.2, |

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|---|---|
| PRD-IPG-3003 | The IPG electronic assembly should be able to withstand (function after experiencing) the following:<br>Mechanical shock at 500 g per ISO 14708-1:19.1 |
| PRD-IPG-3004 | The IPG electronic assembly should be able to withstand (function after experiencing) the following:<br>Accelerated aging per ISO 14708-1:19-1 |
| PRD-IPG-3005 | The IPG and Charger should be able to meet heat testing during charging per ISO 14708-1:17.1 & EN 60601-1:11.1.2.2 |
| PRD-IPG-3006 | The IPG header will have limited air bubbles per MIL-STD-750-2A (clause 3.1.1.5) where there should be an absence of air bubbles covering more than one-third of the distance from the nearest metal surface to the edge. |

### 6.2 Charger

| PRD ID | Charger Specification Text |
|---|---|
| PRD-CRG-0001 | The mating charging coil to the IPG is housed in the charger such as the WPT coil: 760308100110, Wurth Elektronik |
| PRD-CRG-0002 | The charging activities are managed by a PCBA located in the charger |
| PRD-CRG-0003 | The charger is powered by rechargeable or replaceable batteries |
| PRD-CRG-0004 | The charger contains an indicator that provides feedback to the user on the charge status |
| PRD-CRG-0005 | The charger is enclosed in a plastic enclosure |
| | **Charger Testing** |
| PRD-CRG-3001 | The charger electronic assembly is supported to be able to withstand (function after experiencing) the following:<br>Shelf drop per ISO 14708-1:10.1, 23.2, 23.7, |
| PRD-CRG-3002 | The charger electronic assembly is supported to be able to withstand (function after experiencing) the following:<br>Vibration test at 5-500 Hz for 30 mins per ISO 14708-1:23.2, |
| PRD-CRG-3003 | The charger electronic assembly is supported to be able to withstand (function after experiencing) the following:<br>Mechanical shock at 500 g per ISO 14708-1:19.1 |
| PRD-CRG-3004 | The IPG and Charger should be able to meet heat testing during charging per ISO 14708-1:17.1 & EN 60601-1:11.1.2.2 |