1.0 Purpose

The purpose of this document is to compare initial design to 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
PRD	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 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.

6.0 Mechanical Specifications

If specification has been met column “Has design intent been met” is indicated with “Yes”. If the design intent has been met, but needs testing to confirm it is indicated with “Test”. If the design intent is not met or does not appear to be met it is indicated with “No”.

6.1 IPG

PRD ID	IPG Specification Text	Has Design Intent Been Met?
PRD-IPG-0001	The IPG incorporates 16 Lead Contacts	Yes
PRD-IPG-0002	The contacts are arranged in the header in 4 sets of 4 contacts.	Yes
PRD-IPG-0003	With only a small modification, the header can be arranged with one or both lead bores in an 8 contact configuration.	Yes
PRD-IPG-0004	The lead connectors are Bal Seal Sygnus 2.8 mm pitch connectors with accompanying silicone seals	Yes
PRD-IPG-0005	Bluetooth or WiFi antenna (2.4 GHz capable) is located in the header	Yes
PRD-IPG-0006	Hermetic assembly accommodates 2 Quallion QL0200I EnerSys Batteries or similar	Yes
PRD-IPG-0007	Hermetic Assembly encloses a charge coil similar to WPT coil 760308101107, Wurth Elektronik	Yes
PRD-IPG-0008	Hermetic Assembly encloses the suppled PCBA	Yes
PRD-IPG-0009	A nest that supports and stabilizes the PCBA, coil, and batteries within the hermetic assembly	Yes
PRD-IPG-	The IPG electronics assembly will be hermetically sealed in an	Test

0010	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	Yes
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.	Yes
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	Yes
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.	Yes
PRD-IPG-0015	The IPG outermost dimensions are less than 2” X 2.6” X 0.5”	Yes
	IPG Materials	
PRD-IPG-2001	All the materials of the IPG Kit that are in contact with the body are selected for known biocompatibility.	Yes
PRD-IPG-2002	The IPG case is be made of Grade 23 titanium	Yes
PRD-IPG-2003	The IPG header is made of epoxy (EPOTEK 301) to enclose the header components	Yes
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	Yes
PRD-IPG-2005	The Bal Seals are made of MP35N housing with Pt-Ir springs and incorporates Med-4850 silicone spacer	Yes
PRD-IPG-2006	A connector block and set screw are made of 316L	Yes
	IPG Testing	
PRD-IPG-3001	The IPG electronic assembly should be able to withstand (function after experiencing) the following: Shelf drop per ISO 14708-1:10.1, 23.2, 23.7,	Test
PRD-IPG-3002	The IPG electronic assembly should be able to withstand (function after experiencing) the following: Vibration test at 5-500 Hz for 30 mins per ISO 14708-1:23.2,	Test
PRD-IPG-3003	The IPG electronic assembly should be able to withstand (function after experiencing) the following: Mechanical shock at 500 g per ISO 14708-1:19.1	Test

PRD-IPG-3004	The IPG electronic assembly should be able to withstand (function after experiencing) the following: Accelerated aging per ISO 14708-1:19-1	Test
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	Test
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.	Test

6.2 Charger

PRD ID	Charger Specification Text	Has Design Intent Been Met?
PRD-CRG-0001	The mating charging coil to the IPG is housed in the charger such as the WPT coil: 760308100110, Wurth Elektronik	Yes
PRD-CRG-0002	The charging activities are managed by a PCBA located in the charger	Yes
PRD-CRG-0003	The charger is powered by rechargeable or replaceable batteries	Yes
PRD-CRG-0004	The charger contains an indicator that provides feedback to the user on the charge status	Yes
PRD-CRG-0005	The charger is enclosed in a plastic enclosure	Yes
	Charger Testing	
PRD-CRG-3001	The charger electronic assembly is supported to be able to withstand (function after experiencing) the following: Shelf drop per ISO 14708-1:10.1, 23.2, 23.7,	Test
PRD-CRG-3002	The charger electronic assembly is supported to be able to withstand (function after experiencing) the following: Vibration test at 5-500 Hz for 30 mins per ISO 14708-1:23.2,	Test
PRD-CRG-3003	The charger electronic assembly is supported to be able to withstand (function after experiencing) the following: Mechanical shock at 500 g per ISO 14708-1:19.1	Test
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	Test