1. Purpose

The purpose of this document is to summarize how The Hornet IPG and Charger will be tested to show that the design, construction and functionality of the device meets design and functionality requirements and complies with applicable standards.

2. Scope

This document is valid for the Hornet IPG and Charger. The test plan outlined in this document is progressive and may be released at various stages prior to finalization. This document includes an overview of applicable testing requirements, equipment, and documentation.

3. References

Document No.	Title
ISO 14708-1	Implants for surgery – Active Implantable Medical Devices
	ISO 11607-1:2006 and ASTM F1980-07(2011)

4. Definitions

Abbreviation or Term	Definition
DVT	Design Verification Test
Engineering Bench Level Test	Also known as Engineering Design Verification. Prototype samples are created and subjected to internal and external testing to verify that design requirements and specifications are being met. The results from these tests will determine if the product gets released to Production.
IPG	Implantable Pulse Generator

5. 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. Methods

Each test will be summarized via an approved quality management system controlled protocol. The test will be conducted per the protocol with records and deviations recorded. Results and conclusions along with any needed discussion and recommendations will be documented in a report. The test results will be compiled and summarized in a Test Report or appendix.

7. Sample Size Strategy

Three to nine samples for each test will be used.

8. DVT Test Details

Test	Testing Details	
Accelerated Aging (Device)	Purpose	▶Ensure IPG meets requirements, standards, and performance characteristics for the anticipated lifetime of the device.
	Standards	▶ISO 14708-1:19-1
	Acceptance Criteria	▶Meets functional specifications at appropriate time points and at the final timepoint. ▶There is no visible corrosion or delamination apparent that would lead to connection of two conducting surfaces. ▶No unacceptable risks become evident as the device ages.
	Equipment	▶Oven ▶RH Meter ▶Timer ▶Temperature Probe and Meter
	Test Set Up	▶Consider the composition, morphology, thermal transitions, additives or other chemical properties present in materials. ▶ Assumptions: - Conditioned in 0.9% sodium chlorine bath heated to 55 degrees C per accelerated aging standards outlined in ISO 11607-1:2006 and ASTM F1980-07(2011) - Accelerating Aging Temperature 55 degrees C - Nominal temperature 37 degrees C - Q10 value of 2.0 - With the above calculations the testing timepoints: ○ 3 months = 26 days ○ 12 months = 52 days

Test	Testing Details	
		○ 24 months = 105 days ○ 36 months = 314 days ○ 48 months = 419 days ○ 60 months = 524 days - Team may decide to increase temperature depending on battery and timepoint calculation will change accordingly ►Place the Aging Parts in prepared saline bath and place in designated oven and record start time and date. Record temperature measurement calibration information. ►Age Samples at Accelerated Aging Temperature, and in parallel, age samples at room temperature. ►At the end of each Aging Test Time Interval, visually inspect device and verify performance requirements of the device. Place device back in chamber after testing to continue the conditioning.
	Report	►Generate Report, including aging conditions (test temperature, humidity, cycle, ambient temperature, time frame, sample sizes, time intervals of sampling, and specific tests at each time interval). Record all instruments used and calibration information. Document test standard references and methods of evaluation.

Test	Testing Details	
Heating Test During Normal Operation	Purpose	►Ensure outer surface of the IPG does not supply heat to patient greater than 2C above body temperature.
	Standards	►ISO 14708-1:17.1; EN 60601-1:11.1.2.2
	Acceptance Criteria	►Temperature of external surfaces not greater than 2C over 37C surrounding body temperature when in normal operation or in an single component failure. ►Device enters fault condition if surface temperature exceeds 41C.
	Equipment	►Temperature Probe(s) ►Calibrated Temperature Meter ►Calibrated Oven ►Kapton Tape

Test	Testing Details	
		▶Device specific charging equipment ▶DI Water ▶Water Tank
	Test Set Up	▶Prepare samples ▶Firmly attach the temperature probe(s) to the device using Kapton Tape. Attach multiple probes to the device to ensure temperature does not significantly vary across the external surface of the enclosure. Small devices may only require a single probe. ▶Preheat the oven to 37C. ▶Place the device and charging equipment into the oven in a manner the device charging will replicate behavior of the implanted system ▶Begin to execute charging protocol, ensuring data is being logged. ▶Allow the device to run in each mode of normal stimulation through full anticipated charge and discharge cycles. ▶Once modal testing is complete, increase the oven temperature to 42C. Monitor the temperature probes and device communication or stimulation to ensure the device enters a fault condition at 41C.
	Report	▶Generate Report, including equipment information, sample information, a description of the test method used, and a table of data describing probe locations and temperature experienced during normal use, and a summary of results.

Qualification Test	Testing Details	
Vibration Mechanical Force Testing	Purpose	▶Ensure IPG has been constructed to withstand mechanical forces which might occur during normal use, including the time before implant.
	Standards	▶ISO 14708-3: 23.2 (2017); EN 60068-2-47; EN 60068-2-64
	Acceptance Criteria	▶The device shall pass a functional test at the completion of testing.
	Equipment	▶Mechanical Vibration and Shock System
	Test Set Up	▶Test Conditions: a) Test Frequency Range: 5Hz to 500Hz b) Acceleration spectral density: 0.7(m/s2)2/Hz c) Shape of Acceleration Spectral Density Curve: Flat Horizontal, 5 Hz to

Qualification Test	Testing Details	
		500Hz d) Duration of Testing: 30 minutes in each of three mutually perpendicular axes ►Perform a functional test to ensure the device meets all applicable requirements.
	Report	►Generate a report, including a description of equipment with calibration information, a description of the samples tested, observations during or after testing, and a summary of post test performance evaluations.

Qualification Test	Testing Details	
Minor Mechanical Shock Testing	Purpose	►Ensure device can endure minor mechanical shocks caused by mishandling during implant procedure
	Standards	►ISO 14708-3: 23.7 (2017) and EN 60068-2-27
	Acceptance Criteria	►The device shall pass a functional test at the completion of testing.
	Equipment	►Mechanical Shock Testing Equipment
	Test Set Up	►Test Specifications: a) Shock Shape: Half sine or Haversine b) Severity: Peak Acceleration: 5000m/s^2 (500g) c) Duration of Shock: 1ms d) Shock Details: Six total; One shock in each direction along each axis XYZ ►Perform a functional test to ensure the device meets all applicable requirements.
	Report	►Generate a report, including a description of equipment with calibration information, a description of the samples tested, observations during or after testing, and a summary of post test performance evaluations.

Qualification Test	Testing Details	
Drop & Impact Testing	Purpose	►To ensure sales packaging can withstand dropping, stacking, vibration, and temperature for storage and handling
	Standards	►ISO 14708-1: 10.1 23.2, 23.7

Qualification Test	Testing Details	
		▶ASTM D5276 ▶ASTM D4332
	Acceptance Criteria	▶The device shall pass a functional test at the completion of testing. ▶The device passes a visual inspection at the completion of testing
	Equipment	▶Humidity oven
	Test Set Up	▶Prepare and package IPG samples ▶Prepare Charger unpackaged ▶Condition the parts per ASTM D4332 in humidity oven ▶Perform drop test at drop from a distance of 1 m with packaged IPG and unpackaged charger onto a standard manufacturing facility floor. When complete, perform functional testing ▶Stack 10 IPG and 10 Charger packages let sit for 24 hours, after 24 hours functionally test the bottom IPG and charger ▶Perform vibration testing in accordance with ISO 14708-1:23.2 and complete functional test
	Report	▶Generate Report

8.1. Other Testing

Qualification Test	Testing Details	
Hermeticity Testing	Purpose	▶Ensure the IPG meets hermeticity requirements.
	Standards	▶MIL-STD 883K 1014.15 and MIL-STD 750-1A-CHG-2 1071.16
	Acceptance Criteria	▶leak rate shall be less than 1 X 10-8 with 100% He
	Equipment	▶Pfeiffer Leak Detector ▶Test Chamber Tool
	Test Set Up	▶Ensure Leak Detector is calibrated and preventative maintenance is completed. ▶Startup the equipment per the manufacturer manual. ▶Place the Test Chamber on the vacuum port. ▶Perform a test to ensure the chamber is reading the correct value with no IPG installed

Qualification Test	Testing Details	
		▶Once empty chamber performance has been verified, ▶Place the first IPG into the chamber, and initiate a leak test ▶Record the result and indicate pass or fail according to the leak rate specified on the assembly drawing. ▶Continue testing for all samples required by
	Report	▶Generate Report

Qualification Test	Testing Details	
Shear Force Testing	Purpose	▶Ensure IPG Header is sufficiently adhered to the device enclosure
	Standards	▶EN 60601-1: 15.3.2
	Acceptance Criteria	▶Withstands 250N +/-10N for a period of 5 seconds without sustaining damage
	Equipment	▶The ▶Mitutoyo ▶Shear Test Tool ▶Timer
	Test Set Up	▶Prepare samples with the following considerations: • Batteries should not be included in shear test devices • Other device internals may or may not be included in shear test devices ▶Select an appropriate Force Gauge (compression greater than 260N) and install in the (Force Testing Machine) ▶ Attach the Shear Test Tool Part A to the force guage ▶Place the IPG into the fixture ▶Align the components of the tool such that the base securely holds the IPG without contacting the header, and the header force block nearly contacts the header without contacting the IPG enclosure. ▶Obtain and wear safety glasses and ensure area is clear ▶Zero the force gauge, if required, prior to starting the test ▶Prepare the timer ▶Apply 250N, +/- 10N of force to the IPG. Do not exceed 260N ▶Start the timer once 250N +/- 10N is applied. Ensure the force is applied for a minimum of 5 seconds.

Qualification Test	Testing Details	
		► Remove the compression force from the IPG ► With the IPG in the test fixture, inspect for damage or delamination at the header/enclosure interface. ► Remove the IPG from the test fixture and repeat the inspection for damage. Record any damage observed during either inspection. ► Repeat the test for all Header Shear force samples
	Report	►Generate Report