1. Purpose

The purpose of this document is to summarize how The Hornet Leads 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 Leads. 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 & 3	Implants for surgery – Active Implantable Medical Devices
	ISO 11607-1:2006 and ASTM F1980-07(2011)
BS EN 45502-2-1:2003	Active Implantable Medical Devices Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers)

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. This document is focused on leads only.

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. This number is to show the ability of the lead to meet the shown criteria. For formal DVT testing for human use these values will need to be reviewed per use case based on risk and application to evaluate if test and sample size can be utilized or if the test needs to be supplemented or repeated. Planned testing units are represented below for each test.

8. DVT Test Details

8.1. Tests that require pre-conditioning

8.1.1. Baseline functional lead measurements shall be recorded and cataloged.

8.1.2. Ensure measurements for each lead it clearly identifiable.

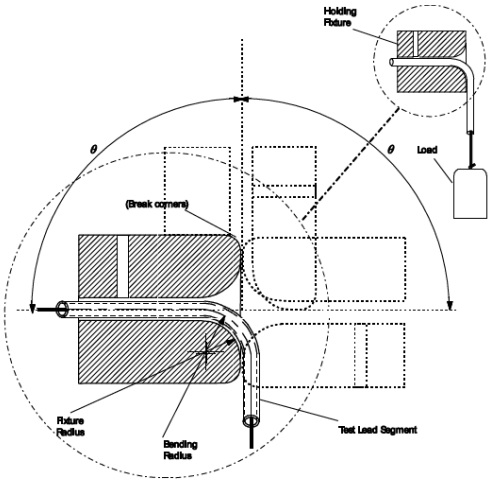
8.1.3. Preconditioning protocol:

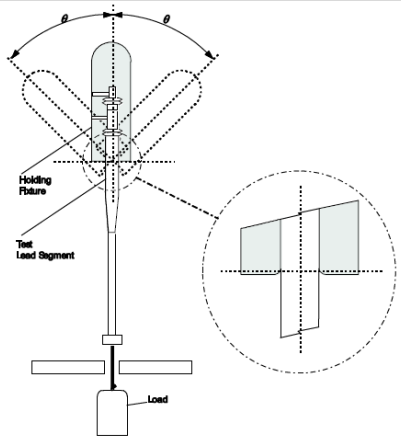
8.1.3.1 Pre-conditioning bath of 9 g/l saline at 37 deg C +/- 5 deg C submerged for 10 days.

8.1.3.2 Immediately prior to testing the lead shall be rinsed in distilled or deionized water, and then wiped free of surface water.

Test	Testing Details	
Lead Body Pull Test at 5 N	Purpose	►Leads shall withstand the tensile forces that might occur after implantation, without fracture of any conductors or joints or breaching of any functional electrical isolation.
	Standards	►ISO 14708-2:23.3
	Acceptance Criteria	► Leads exhibits no permanent elongation in exceeds of 5% nor any permanent functional damage; ►The continuity measurements do not change from baseline to after conditioning; ►The leakage current measured between each conductor and the reference electrode and between any two conductors that have an exposed conductive surface intended for contact with tissue is <= 2 mA during the voltage application.
	Equipment	►preconditioning bath of approximately 9 g/l saline at 37 deg C +/- 5 °C, ►a tensile load tester,

Test	Testing Details	
		►a resistance meter, ►a reference electrode plate having a noble metal surface with a minimum area of 500 mm2 that can be located in the test bath (same as precondition-ing bath requirements) ►a leakage current tester, capable of applying 100 V and supplying a current of at least 2 mA.
	Lead Samples	►20 cm SNS leads will be utilized. ►SNS lead was chosen because the quadripolar leads represent the worst case of lead body stresses with 4 filar vs. 2 filar. ►Qty 9 as representative samples will be used.
	Test Set Up	►After conditioning: ►The LEAD shall be fitted in the tensile tester, clamped at the metallic surface of the LEAD connector pin and at the appropriate point on the distal end of the LEAD. The distance between the lamping points shall be measured. ► The lead shall be subjected to a tensile load, limited to a value causing 20% elongation, otherwise increased to at least 5N. The tensile load shall be sustained for at least 1 min, then relieved. ►The tensile load application shall be repeated for each combination of distal end tip and lead connector pin. This may be accomplished by using multiple leads as the test sample. ►The electrical continuity of each conduction path shall be verified by measuring DC resistance ►The insulation integrity of each lead shall be verified by immersing the outer covering, other than 20 mm of any exposed conductive surface, in the test bath. The test specimen(s) shall be placed in the test bath within 30 min of removal from the preconditioning bath and shall be immersed in the test bath for a minimum of 1 h before proceeding. The test specimen shall be positioned in the test bath so that the lead body is not less than 50 mm nor more than 200 mm from the reference electrode plate. ►The insulation shall then be subjected to a 100 V +/- V DC test potential between each conductor and the reference electrode and between any two conductors that have an exposed conductive surface intended for contact with tissue. The test voltage shall attain the full value within 0,1 s to 5 s. The test potential shall be maintained at full value for at least 15 s before being lowered to zero.
	Report	► Generate Report

Test	Testing Details	
Lead Flexure Cycling Test	Purpose	►Implantable leads shall withstand the flexural stresses that might occur after implantation, without fracture of any conductor. ►Test 1 to be conducted to be conducted 5 cm from the connecting features of stimulation or sensing on the distal end on lead body. ►Test 2 to be conducted on each type of uniform lead body on the proximal end construction for each lead type.
	Standards	►ISO14708-2:23.5
	Acceptance Criteria	► Measured resistance and conductance has not significantly varied from baseline values.
	Equipment	►a resistance meter, ►functional test equipment ►Figure 123 Test fixture:  **Figure 123 — Conductor flex test fixture** ►Figure 124 Test Fixtures

Test	Testing Details	
		 **Figure 124 — Connector flex test fixture**
	Lead Samples	►20 cm leads will be utilized. ►Qty 3 SNS leads as representative samples will be used of a quadripolar lead body and Qty 3 Cuff/VNS lead samples will be used of a bipolar lead body sample. ►A mix of SNS (4 filar) and VNS leads (2 filar) will be utilized to compare representative samples for both lead configurations. The test plan can be used across different lead applications due to the test purpose as outlined above.
	Test Set Up	►Perform preconditioning Test 1: Flexible lead segments – 5 cm from distal end ►Using special holding fixture (see figure 123 from standard). The inside bore of the fixture shall be no greater than 110% of the diameter of the lead segment under test. At the lower end of the fixture, the inside surface shall be formed into a bell mouth having a radius such that, when the test segment conforms to the contour of the fixture, the center line of the test segment forms a 6 mm +/- 0.1 mm center line bending radius ►The fixture shall be mounted in a machine that can oscillate the fixture 90 +0/-5 degrees from the vertical and forces the test segment to flex in the bell mouth of the fixture. The lead test segment shall be mounted to hang vertically under gravity in the holding fixture, oriented in the worst-case test condition when the test segment allows multiple orientations. A load sufficient to ensure that the center line of the test segment conforms to the bending radius shall be attached to the lower end of a thin, flexible line (cord) strung through the test segment. For LEAD bodies with no accessible

Test	Testing Details	
		lumen, a minimal tensile load may be applied directly to the test segment, so that it conforms to the bending radius. ►The fixture shall be oscillated through an angle 90 degrees +0/-5 deg each side of vertical at a rate of approximately 2 Hz for a minimum of 47,000 cycles. (minimize vibration). ►The test shall be repeated for each unique uniform flexible part of the lead body. ►Post flexure measure resistance and functional conductivity Test 2: Lead proximal connector joints between lead and connector body – proximal end ► Using special holding fixture (see figure 124 from standard) (similar in form to header). The holding fixture shall be made of rigid materials with representative corners and materials to header. ►The holding fixture shall be mounted in a machine that can rotate the fixture 45 deg +/- 2 deg from the vertical (figure 124 from standard). The center of rotation shall be in the plane where the rounded corners of the holding fixture begin. The holding fixture shall allow the lead connector an attached lead segment to hang vertically under gravity. The lead connector shall be fitted into the holding fixture, oriented in the worst-case test condition and retained by the set screw mechanism. ►A load shall be attached to the lead segment 10 cm +/- 0.5 cm from the center of rotation of the holding fixture. The load attachment mechanism shall ensure that there is no relative motion between the conductor and the tubing at the point of attachment. The load shall be 100 g +/- 5 g (including the attachment mechanism). ►The holding fixture shall then be oscillated 45 deg +/- 2 degrees each side of vertical at a rate of approximately 2 Hz for a minimum of 82,000 cycles. ►The test shall be repeated for each joint in the lead body. ►Post flexure measure resistance and functional conductivity
	Report	►Generate Report

Qualification Test	Testing Details	
Lead Connector	Purpose	► Demonstrate the retention force provided by the implantable connector shall be greater than or equal to 10 N. For the lead to header and lead to

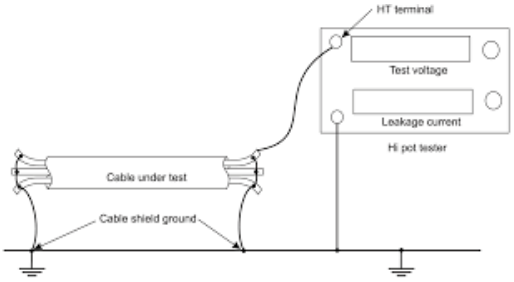
Qualification Test	Testing Details	
Pull Test at 10 N		interconnect.
	Standards	►ISO 14708-2: 23.6
	Acceptance Criteria	►The lead shall not be disconnected at value of 10 N or less.
	Equipment	► The insertion and removal force will be measured by the Instron S/N 3367Q1264. ► Saline bath, approximately 9 g/l at 37oC ± 5oC
	Lead Samples	►20 cm leads will be utilized. ►Qty 3 SNS leads as representative samples will be used of a quadripolar lead body and Qty 3 Cuff/VNS lead samples will be used of a bipolar lead body sample. ►A mix of SNS (4 filar) and VNS leads (2 filar) will be utilized to compare representative samples for both lead configurations. The test plan can be used across different lead applications due to the test purpose as outlined above.
	Test Set Up	► The implantable connector pair shall be mated and immersed in a saline bath, approximately 9 g/l at 37oC ± 5oC, for a minimum of 10 days. ► Remove the lead from the saline bath. ► Subject the lead to header to straight pull of 10 N +/- 0.5 N for a minimum of 10 seconds.
	Report	►Generate report

8.2. Tests that DO NOT require pre-conditioning

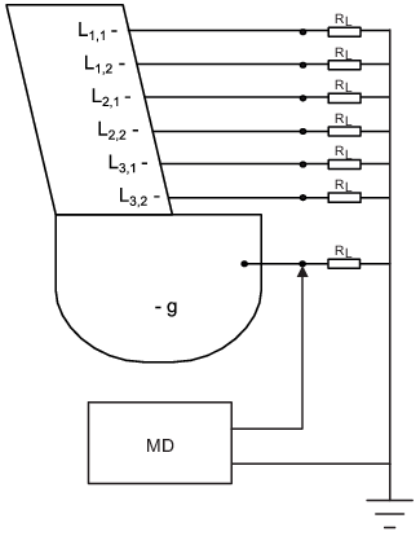
8.2.1. Baseline functional lead measurements shall be recorded and cataloged.

8.2.2. Ensure measurements for each lead it clearly identifiable.

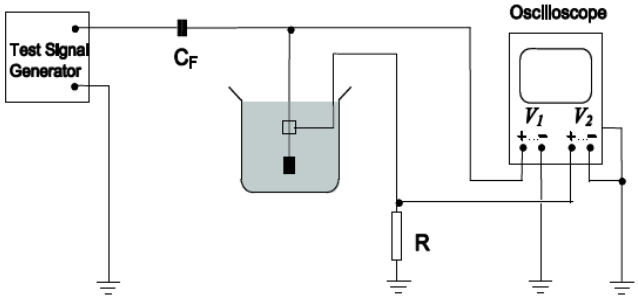
Qualification Test	Testing Details	
Lead leakage current < 10 uA	Purpose	► To test that the lead has effective functional electrical insulation between conductors.
	Standards	►ISO 14708-2: 16.1 / IEC 60601-1, IEC 62353
	Acceptance Criteria	►The leads must have no more than 100 uA current leakage when tested to a minimum of 50 V DC in normal condition (NC). ► Type BF – Electrically connected to Patient but not directly to heart

Qualification Test	Testing Details	
		<table><tr><th rowspan="2">Leakage Current</th><th colspan="2">Type B</th><th colspan="2">Type BF</th><th colspan="2">Type CF</th></tr><tr><th>NC</th><th>SFC</th><th>NC</th><th>SFC</th><th>NC</th><th>SFC</th></tr><tr><td>Earth Leakage current</td><td>500uA</td><td>1mA</td><td>500uA</td><td>1mA</td><td>500uA</td><td>1mA</td></tr><tr><td>Enclosure Leakage current</td><td>100uA</td><td>500uA</td><td>100uA</td><td>500uA</td><td>100uA</td><td>500uA</td></tr><tr><td>Patient Leakage current</td><td>100uA</td><td>500uA</td><td>100uA</td><td>500uA</td><td>10uA</td><td>50uA</td></tr></table> NC = Normal Conditions SFC = Single Fault Conditions
	Equipment	► Guardian Electrical Safety Analyzer model 19032 from Chroma System Solutions to measure current leakage.
	Lead Samples	►20 cm leads will be utilized. ►Qty 9 SNS leads as representative samples will be used of a quadripolar lead body as the worst case sample.
	Test Set Up	► High and low leakage current limits will be set to 1 mA. The applied voltage will be set to 50 V DC. 
	Report	►Generate Report

Qualification Test	Testing Details	
Lead DC Charge <= 0.75 UA/mm^2	Purpose	►To confirm the maximum current density at any electrode is no more than 0.75 uA/mm^2. Except for its intended function, an IMPLANTABLE PULSE GENERATOR, when in use, shall be electrically neutral. No d.c. leakage current of more than 1 µA shall occur in any of the current pathways of the CASE TERMINALS and no more than 0.1 µA in the current pathways of any other TERMINAL.
	Standards	►ISO 14708-2: 16.2

Qualification Test	Testing Details	
	Acceptance Criteria	► maximum current density at any electrode is no more than 0.75 uA/mm^2 except for its intended function.
	Equipment	► Guardian Electrical Safety Analyzer model 19032 from Chroma System Solutions to measure current leakage.
	Lead Samples	►40 cm leads will be utilized. ►Qty 9 VNS leads as representative samples will be used of a cuff lead sample as this is the most likely to use high frequency signals, which represents the highest risk for lead DC charge.
	Test Set Up	► The IMPLANTABLE PULSE GENERATOR shall be set to the nominal settings recommended by the MANUFACTURER (i.e. the "factory recommended settings") but with the PULSE AMPLITUDE and PULSE DURATION programmed to the highest available settings. ►Each electrically conductive part of the IMPLANTABLE PULSE GENERATOR in contact with body tissue when the device is implanted shall be identified and connected to a common bus through 500 ? ? 1 % load resistors RL (see Figure 122). For devices with fewer terminals than shown in Figure 122, the associated resistors RL are not used. Example image:  ►Measure the average direct voltage across each load resistor with the measuring device. Steady-state conditions shall be reached before the measurement is made. ►The measurement of the individual terminal currents may be made with a plurality of measuring devices.

Qualification Test	Testing Details	
	Report	▶Generate report

Qualification Test	Testing Details	
Lead contact impedance < 1000 ohm	Purpose	▶Measurement of lead stimulating impedance using in vitro approach
	Standards	▶ ISO 14708-2: 6.2.3
	Acceptance Criteria	▶Resistance is acceptable. Typically < 50 ohms.
	Equipment	▶Oscilloscope ▶Test Signal Generator
	Lead Samples	▶40 cm leads will be utilized. ▶Qty 9 VNS leads as representative samples will be used of a cuff lead sample with the DC charge test.
	Test Set Up	▶ The LEAD shall be inserted into the test body so that the ELECTRODES are at least 10 mm from any fluid boundary. ▶The test signal generator shall be connected through a 33 µF +/- 5 % series film capacitor (CF) to the LEAD, the metal plates and the oscilloscope as shown in Figure 121.  **Figure 121 — Determination of the LEAD PACING IMPEDANCE of a BIPOLAR LEAD** ▶Set the signal generator to provide negative pulses, 65 +/- 5 per minute, amplitude 4 V+/-0.1 V and duration (Tp) of 0.5 ms +/- 0.05 ms. The LEAD current shall be determined by measuring the voltage drop across the 10

Qualification Test	Testing Details	
		ohm +/- 2 % resistor. ►The LEAD stimulation IMPEDANCE (Zp) shall be calculated, using the mean values of voltage and current, by applying the formula: $Z_p = R^* \frac{\int_0^{T_p} V_1 - V_2 dt}{\int_0^{T_p} V_2 dt}$ NOTE See Figure 120 and Figure 121 for definitions of V1 and V2.
	Report	► Generate Report

Qualification Test	Testing Details	
Lead accelerated aging test	Purpose	►Ensure Leads meet requirements, standards, and performance characteristics for the 2 years.
	Standards	►ISO 14708-1:19-1
	Acceptance Criteria	►Meets functional specifications at appropriate time points. ►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
	Lead Samples	►20 cm leads will be utilized. ►Qty 9 VNS leads as representative samples will be used of a cuff lead sample with the DC charge test.
	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)

Qualification Test	Testing Details	

		- 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
		  ○ 24 months = 105 days
		  ○ 36 months = 314 days
		  ○ 48 months = 419 days
		  ○ 60 months = 524 days
		- Team may decide to increase temperature depending on 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.