1 Purpose

This protocol prescribes methods and records results necessary to verify vibration mechanical force testing, minor mechanical shock testing, and drop and impact testing meets requirements for the 3025 Hornet IPG.

2 Scope

This document references specific standards and device requirements to be tested by an external laboratory. This document provides records to ensure testing is performed to the required standards, and results are reviewed at the completion of testing

3 References

Document No.	Title
ISO 14708-3: 23.2	Implants for surgery – Active implantable medical devices – Part 1: General requirements for safety, marking and for information to be provided by the manufacturer, Part 23.2, Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from mechanical forces
EN 60068-2-47	Environmental testing – Part 2-47: Tests – Mounting of specimens for vibration, impact, and similar dynamic tests
EN 60068-2-64	Environmental testing – Part 2-64 – Test Fh: Vibration, broadband random and guidance
ISO 14708-3: 23.7	Implants for surgery – Active implantable medical devices – Part 1: General requirements for safety, marking and for information to be provided by the manufacturer, Part 23.7, Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from mechanical forces
EN 60068-2-27	Environmental testing – Part 2-27: Tests – Test Ea and guidance: Shock
ASTM D5276	Standard Test Method for Drop Test of Loaded Containers by Free Fall
ASTM D4332	Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing

4 Appendices

Appendix:	Title
A	Vibration Mechanical Force Testing Request Form
B	Functional Test Record
C	Additional Notes Area (if required)

5 Definitions

Abbreviation or Term	Definition
DVT	Design Verification Test
IPG	Implantable Pulse Generator

6 Testing Protocol

6.1 Devices will be tested to the following requirements:

6.1.1 Vibration Mechanical Force Testing:

6.1.1.1 Test Frequency Range: 5Hz to 500Hz

6.1.1.2 Acceleration Spectral Density: 0.7(m/s2)2/Hz

6.1.1.3 Shape of Acceleration Spectral Density Curve: Flat Horizontal, 5z to 500 Hz

6.1.1.4 Duration of Testing: 30 minutes in each of three mutually perpendicular axes

6.1.1.5 Functional Testing: Device meets all functional testing requirements after completion of vibration mechanical force testing

6.2 Testing Device Drawing Number:_____

6.3 Functional Test Work Instruction:_____

6.4 **Information for Outsourcing:**

6.4.1 Complete Appendix A, Vibration Mechanical Force Testing Request Form. Submit the form to the anticipated vendor to obtain quoting information and attach the provided quote to this protocol.

6.4.2 Print a copy of the applicable assembly drawing(s) to include with the request form

6.4.3 Print a photograph of the completed devices to include with the request form

Signature:_____ Date:_____

6.5 **Approval:**

A representative from QA must review and approve the specification information and submission for prior to shipment.
Quality Approval to Execute Testing:

Signature:_____ Date:_____

6.6 **Sample Generation**

6.6.1 Describe the origin of the samples used. If new samples where created for this test, describe any deviations, if applicable, that may impact testing:

_____

_____

_____ _____

_____ _____

_____ _____

_____ _____

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_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

Initial:_____ Date:_____

Record Device Serial Numbers Below:

_____

_____

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_____

_____

Initial:_____ Date:_____

6.7 **Lab Testing:**

NOTE: Any testing laboratory that can meet the testing requirements may be used

6.7.1 Complete a pre-testing functional test prior to shipment. Record the results in Appendix B: Functional Test Record

Initial:_____ Date:_____

6.7.2 Ensure the device battery is less than 30% charged prior to shipping.

Initial:_____ Date:_____

6.7.3 Package the devices for shipment as to avoid damage in transit. Include the request form, device drawing and photograph, and any other relevant work order information with the devices.

Initial:_____ Date:_____

6.7.4 Prior to shipping review all paperwork for completeness. Include a review by a quality representative for verification.

Signature:_____Date:_____

(QA) Signature:_____Date:_____

6.7.5 Upon Receipt:

6.7.5.1 Review the provided reports for completeness:

Initial:_____Date:_____

6.7.5.2 Complete a Functional Test, and record the results for each device on Appendix B, Functional Test Record. Attach copies of any functional test reports generated by testing.

Initial:_____Date:_____

6.7.5.3 Attach all lab data to this protocol:

Initial:_____Date:_____
Notes:

_____

_____

_____

_____

_____

7 Approvals

7.1 Verify testing results meet drawing requirements

Initial_____ Date_____

7.2 Quality Approval

7.2.1 Review Protocol

7.2.2 Review Lab Testing Records

7.2.3 Review Appendix B: Functional Test Record

7.2.4 Review Appendix C: Additional Notes Area (if applicable)

7.2.5 Ensure Testing Results are attached

Signature:_____ Date:_____

7.3 Other Approval (If required):

Signature:_____ Date:_____

7.4 Notes (if required):

_____

_____

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Appendix A: Vibration Mechanical Force Testing Request Form

Point of Contact:_____ **Ph.**_____

Bill To: Med-Ally
2040 Bushy Park Rd.
CIMC N. Bldg 6
Goose Creek, SC 29445

Ship to: Med-Ally
2040 Bushy Park Rd.
CIMC N. Bldg 6
Goose Creek, SC 29445

Project Name: Hornet IPG

Product Weight: _____ oz each; _____oz total shipped weight

Quantity to test:_____

Description of Contents: Medical device; Internal Pulse generator consisting of active electronics with Lithium Ion batteries (Voltage and weight) contained in a welded titanium enclosure, with external connections accessible in the attached epoxy header.

Special Handling: BATTERY CHEMISTRY, WEIGHT battery in each device; No other drugs, biologics or hazardous materials included.

Battery Considerations: NOTE: Westpak requires batteries to be UN 38.3 certified with a state of charge <30%, and include MSDS

Max Temperature Exposure:_____ **Min Temp Exposure:**_____

Testing Required: Vibration Mechanical Force Testing in accordance with ISO 14708-3: 23.2, EN 60068-2-47, and EN 60068-2-64, reference method below:
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, 5Hz to 500Hz
d) Duration of Testing: 30 Minutes in each of three mutually perpendicular axes
e) Return devices to Med-Ally upon test completion for Functional Verification
f) Include verification of test methods, dates, times and associated information with returned parts.

QA Signature:_____Date:_____

Appendix B: Functional Test Record

Circle the functional test being completed below:

Pre-Vibration Testing Post-Vibration Testing

Serial #	Pass/Fail	Notes:

Signature:_____ Date:_____Page___ of____

Appendix C: Additional Notes (if required). Notes may be typed or hand written:

Signature:_____ Date:_____ Page___ of____