1 Purpose

This protocol prescribes methods and records results necessary to verify drop and impact testing meets requirements for the Hornet IPG

2 Scope

This document references specific standards and device requirements to be completed at Med-Ally with additional testing 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
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 60068-2-47	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 14708-1: 10.1	Implants for surgery – Active implantable medical devices – Part 1: General requirements for safety, marking and for information to be provided by the manufacturer, Part 10.1, Construction of the SALES PACKAGING
ASTM D5276	Standard Test Method for Drop Test of Loaded Containers by Free Fall
ASTM	Standard Practice for Conditioning Containers, Packages, or

Document No.	Title
D4332	Packaging Components for Testing

4 Appendices

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

5 Definitions

Abbreviation or Term	Definition
DVT	Design Verification Test
IPG	Implantable Pulse Generator
PPM	Parts per Million (by molecule type)

6 Testing Protocol

6.1 Per ISO 14708-1 Sections 10.1, 23.2, 23.7 and associated standards, devices will be tested to the following requirements:

6.1.1 Drop & Impact Testing

6.1.1.1 Parts conditioned per ASTM D4332

6.1.1.2 Pass functional test after test drop from 1 meter onto standard manufacturing floor in accordance with ASTM D5276

6.1.1.3 Pass functional test after 24 hour stack test, as specified in this protocol

6.1.1.4 Pass functional testing at the completion of outsourced vibration testing per ISO 14708-1:23.2

6.2 Tested 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:

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Initial:_____ Date:_____

Record Device Serial Numbers Below:

1. _____

2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____
9. _____
10. _____

Initial:_____ Date:_____

6.7 Preconditioning

6.7.1 Preconditioning step 1

6.7.2 Preconditioning Step 2

6.7.3 Preconditioning Step 3

Initial:_____ Date:_____

6.7.4 Complete Appendix D, Functional Test Record for each device.

Initial:_____ Date:_____

6.7.5 Attach copies of any functional test reports generated by testing.

6.8 Drop Test:

6.8.1 Drop Test Step 1

6.8.2 Drop Test Step 2

6.8.3 Drop Test Step 3

6.8.4 Complete Appendix D, Functional Test Record for each device.

Initial:_____ Date:_____

6.8.5 Attach copies of any functional test reports generated by testing.

6.9 Stack & Compression Test:

6.9.1 Ensure devices, with all accessories required by the applicable assembly drawing, are loaded in final packaging.

Initial:_____ Date:_____

6.9.2 Stack the 10 assembly packages face to face, vertically.

Initial:_____ Date:_____

6.9.3 Print and complete Appendix C, Stack Test Record, indicating the device serial number for the device at the bottom of the 10 device stack. Record the start time of the 24 hour test.

Initial:_____ Date:_____

6.9.4 After a minimum of 24 hours has passed, record the finish time, and remove the device from the bottom of the stack. Perform a functional test and complete Appendix D, Functional Test Record, for the device that was removed from the bottom of the stack. Return the device to the top of the stack, and repeat the 24 hour compression stack test for the device now located at the bottom of the stack. Repeat testing until each device in the stack has been subjected to 24 hour minimum compression, and a stack test record and functional test record is completed for each of the 10 devices. Complete the initial/date of this step after all devices have been completed.

Initial:_____ Date:_____

6.9.5 Print all functional test data associated with the devices generated by the functional test.

Initial:_____ Date:_____

6.9.6 Submit paperwork to quality to ensure completeness and acceptance of test results.

QA Initial:_____ Date:_____

Notes:

_____

_____

_____

6.10 **Lab Vibration Mechanical Force Testing:**

NOTE: Any testing laboratory that is able to perform the tests prescribed in this protocol and is an approved supplier may be used for vibration mechanical force testing.

6.10.1 BATTERY LEVEL VERIFICATION

6.10.1.1 Prior to shipment, batteries shall be depleted to less than 30% capacity. Initial and date below when battery level has been verified:

Initial:_____ Date:_____

6.10.2 PACKAGE THE DEVICES

6.10.3 Package the devices to prevent damage during shipment, and in accordance with all applicable shipping requirements (hazard labels, etc.)

6.10.3.1 Include a copy of Appendix A, Vibration Mechanical Force Testing Request Form, a copy of the assembly drawing, and a copy of the reference device photograph.

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

Signature:_____Date:_____

(QA)
Signature:_____Date:_____

6.10.5 Upon Receipt of Tested Devices:

6.10.5.1 Review the provided reports for completeness:

Initial:_____Date:_____

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

Initial:_____Date:_____

6.10.5.3 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 Appendix A: Vibration Mechanical Force Testing Request Form
7.2.3 Review Appendix B: Drop Test Record
7.2.4 Review Appendix C: Stack Test Record
7.2.5 Review Appendix D: Functional Test Record
7.2.6 Review Appendix E: Additional Notes (if applicable)
7.2.7 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 BATTERY CHEMISTRY batteries (Voltage and weight) containted 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: Drop Test Record

Serial Number:_____

Pre-Drop Visual Inspection. Note visual anomalies in packaging or device :

_____

_____

_____

Drop Height:_____

Post-Drop Visual Inspection. Verify sterile barrier is not compromised:

_____

_____

_____

Functional Test Complete (initial/date):_____

Signature:_____ Date:_____ Page___ of____

Appendix B: Drop Test Record

Sample #	Pass/Fail	Comments

Signature:_____ Date:_____Page___ of____

Appendix C: Stack Test Record

Serial Number:_____

Start Date:_____ Start Time:_____

Finish Date:_____ Finish Time:_____

Total Time In Stack:_____

Functional Test Complete (initial/date):_____

Signature:_____ Date:_____

Serial Number:_____

Start Date:_____ Start Time:_____

Finish Date:_____ Finish Time:_____

Total Time In Stack:_____

Functional Test Complete (initial/date):_____

Signature:_____ Date:_____ Page___ of____

Appendix D: Functional Test Record

Circle the functional test being completed below:

Pre-Conditioning Post-Drop Post-Stack Post-Vibration

Serial #	Pass/Fail	Notes:

Signature:_____ Date:_____Page___ of____

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

Signature:_____ Date:_____ Page___ of____