



Hornet IPG

Shear Force Testing Protocol

Effective Date:

Rev:

Pg. 1 of 8

1 Purpose

This protocol prescribes methods and records results to ensure the 3025 Hornet IPG adheres to shear testing standards. This protocol is based on ISO standards with reference to specific methods established at Med-Ally. This protocol is intended to be edited to meet the needs of each project at the time of execution without requiring revision of the template.

2 Scope

This document details methods for verification testing to ensure devices meet standards requirements for shear force, and forms to record testing results.

3 References

Document No.	Title
EN 60601-1: 15.3.2	ANSI/AAMI Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

4 Appendices

Appendix:	Title
A	Shear Force Testing Record
B	Additional Notes Area (if required)

5 Definitions

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

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Hornet IPG		
Shear Force Testing Protocol		
Effective Date:	Rev:	Pg. 2 of 8

6 Testing Protocol

6.1 Per the applicable standards, a push test shall be conducted to ensure suitable adhesion between the device header and enclosure. Failure of the push test occurs if the header detaches or delaminates when a force of 250N +/- 10N is applied for a period of 5 seconds, or if damage or other unacceptable risks are induced by the execution of the test. Select the test method applicable to this device (check all that apply):

6.1.1 250N +/- 10N applied for a period of 5 seconds

6.1.2 Post Testing Functional Requirements:

6.2 Finished Device Drawing Number(s):

Initial: Date:

6.3 Approval:

A representative from QA must review and approve the specification information to ensure accuracy of test protocol. Quality Approval to Execute Testing:

Signature: Date:

6.4 Sample Generation

6.4.1 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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Hornet IPG		
Shear Force Testing Protocol		
Effective Date:	Rev:	Pg. 3 of 8

Initial: _____ Date: _____

6.5 Equipment Information:

6.5.1 Equipment used for testing:

Force Gauge Asset Number: _____

Last Cal: _____ Cal Due: _____

Force Tester Asset Number: _____

Last Cal: _____ Cal Due: _____

Tooling Description: _____

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Hornet IPG

Shear Force Testing Protocol

Effective Date:

Rev:

Pg. 4 of 8

Timer Asset Number: _____

Notes (if required): _____

Initial: _____ Date: _____

- 6.5.2 Place the first sample into the holding fixture. Align the device so the push tool (30mm diameter or other if required) is touching only the header, and will not interfere with the enclosure as force is applied to the device.

Operator Initial: _____ Date: _____

- 6.5.3 Set the travel speed of the force tester to 1" per minute, or another slow speed that will allow the operator to stop the movement of the tester once a minimum force of 240N is achieved. Alternatively, if the force tester is properly equipped, set the desired force to 250N for an automated test.

Operator Initial: _____ Date: _____

- 6.5.4 Wearing safety glasses, and while observing the header for signs of delamination, initiate the test by activating compression on the header. Once 240N+ is achieved, stop the motion of the force tester and start a timer set to 10 seconds.

Operator Initial: _____ Date: _____

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Hornet IPG		
Shear Force Testing Protocol		
Effective Date:	Rev:	Pg. 5 of 8

6.5.5 After the timer has indicated 10s has elapsed, note the final force measurement to ensure 240N+ was held for the duration of the test. Record the final test value in the applicable column of appendix A. If a value of 260N+, or in excess of the rest requirement was obtained, and no damage was observed, the sample should be considered a “Pass” as it has withstood forces in excess of the requirement. Inspect the devices for unacceptable damage or unacceptable risks induced by testing.

Operator Initial: _____ Date: _____

6.5.6 After all samples have been tested, perform a functional test to ensure devices maintain anticipated performance:

Work Instruction: _____

Other Functional Test Verification (if required):

Operator Initial: _____ Date: _____

6.5.7 After all samples have been completed, a quality representative shall inspect the devices for damage, delamination, of unacceptable risks induced by testing. Review functional reports to ensure all samples pass.

QA Initial: _____ Date: _____



Hornet IPG		
Shear Force Testing Protocol		
Effective Date:	Rev:	Pg. 6 of 8

7 Approvals

7.1 Verify testing results meet drawing requirements and test standards

Initial_____ Date_____

7.2 Quality Approval

- 7.2.1 Review Protocol
- 7.2.2 Review Appendix A: Shear Force Testing Record
- 7.2.3 Review Appendix B: Additional Notes

Signature:_____ Date:_____

7.3 Other Approval (If required):

Signature:_____ Date:_____

7.4 Notes (if required):



Hornet IPG		
Shear Force Testing Protocol		
Effective Date:	Rev:	Pg. 7 of 8

Appendix A: Shear Force Testing Record

Sample #	Final Force (N)	Time 5s+ (Initial)	Visual Inspection Pass/Fail	Functional Test Pass/Fail	Notes:

Signature: _____ Date: _____ Page ____ of ____



Hornet IPG		
Shear Force Testing Protocol		
Effective Date:	Rev:	Pg. 8 of 8

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

Signature: _____ Date: _____ Page ____ of ____