

Hornet IPG				
Shear Force Testing Protocol				
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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
Α	Shear Force Testing Record
В	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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between the dev delaminates whe	cable standards, a push ice header and enclosurd n a force of 250N +/- 10l ks are induced by the ex	e. Failure of the pus N is applied for a pe	sh test occurs if t eriod of 5 second	he header detaches or ls, or if damage or othel
6.1.1	250N +/- 10N applied 1	for a period of 5 sec	conds	
6.1.2 Post	Testing Functional Requ	uirements:		
6.2 Finished De	vice Drawing Number(s	s):		
0.2		-7-		
Initial:	Date:	:		
6.3 Approval:				
	from QA must review an Quality Approval to Exect		ification informat	tion to ensure accuracy
		τ	Date:	
6.4 Sample Gen	eration			
	ribe the origin of the san deviations, if applicable			reated for this test,
				

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Initia	al: Date:			
6.5 Equipment	Information:			
	ipment used for testing:			
F	O come A continued as			
For	ce Gauge Asset Number:			
Las	t Cal: C	Cal Due:		
For	ce Tester Asset Number:	· · · · · · · · · · · · · · · · · · ·		
Las	t Cal:C	al Due:		
Tod	ling Description:			
				

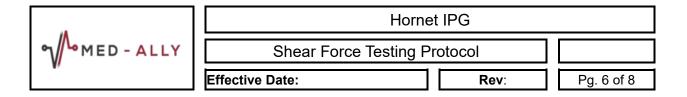
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Tin	ner Asset Number:				
Not	es (if required):				
 -					
					
Init	al: Da	te:			
diameter or	ce the first sample into to other if required) is tou is force is applied to the	ching only the hea			
Ор	erator Initial:	Date	:		
allow the op	the travel speed of the perator to stop the move alternatively, if the force ed test.	ement of the tester	once a minimum fo	rce of 240N is	
Ор	erator Initial:	Date	:		
initiate the t	aring safety glasses, an est by activating compr le force tester and start	ession on the head	der. Once 240N+ is		

Operator Initial:______ Date:____

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ensure 240l column of a and no dam forces in ex	r the timer has indicated 10 N+ was held for the duratio ppendix A. If a value of 260 age was observed, the sar cess of the requirement. In le risks induced by testing.	n of the test. Recor DN+, or in excess on the should be conspect the devices for	d the final test f the rest requi sidered a "Pas	value in the applicable irement was obtained, ss" as it has withstood
Оре	erator Initial:	Date:		
	r all samples have been te performance:	sted, perform a fun	ctional test to	ensure devices maintaiı
Wor	k Instruction:			
Otho	er Functional Test Verificat	ion (if required):		
		D. (
6.5.7 Afte	erator Initial: r all samples have been co damage, delamination, of u	mpleted, a quality i	representative	shall inspect the

QA Initial:______ Date:_____

reports to ensure all samples pass.



7	Approvals 7.1 Verify	Approvals 7.1 Verify testing results meet drawing requirements and test standards				
	Initial Date					
	7.2.1 7.2.2	ity Approval Review Protocol Review Appendix A: Shea Review Appendix B: Addit	ar Force Testing Record			
	Signatur	re: r Approval (If required):	Date:			
	Signatur 7.4 Note	re:s (if required):	Date:			

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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
Signature:	Date:	Page of

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

Signature:	Date:	Page of