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Heat During Normal Operation	Testing Protocol	
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### 1 Purpose

This protocol prescribes methods and records results to ensure the 3025 Hornet IPG adheres to heat output standards during normal operation. 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 heat output, and forms to record testing results.

#### 3 References

Document No.	Title
IEC 60601- 1:11.1.2.2	ANSI/AAMI ES60601-1:2005, Medical electrical equipment, Part 1: General requirements for basic safety and essential performance
ISO 14708- 1:17	Implants for surgery – Active implantable medical devices – Part 1: General requirements for safety, marking and for information to be provided by the manufacturer

# 4 Appendices

Appendix:	Title
Α	Operational Mode Temperature Verification Form
В	Temperature Fault Verification Form
С	Additional Notes Area (if required)

## 5 Definitions

Abbreviation or Term	Definition
DVT	Design Verification Test
IPG	Implantable Pulse Generator
PRD	Product Requirements Document

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# **6 Testing Protocol**

- 6.1 Per the applicable standards, the outer surfaces of an implantable medical device shall not supply excessive heat to the patient in any mode of normal operation, or in the event of a single component failure. Failure of this verification occurs if external surfaces of the IPG exceed temperatures greater than 2 degrees Celsius, or if the device does not enter a fault condition in excess of 41 degrees Celsius. Select the requirements applicable to this device (check all that apply):
  - 6.1.1 Device(s) external surfaces shall not exceed 41 degree Celsius in any normal mode of operation
  - 6.1.2 Device(s) shall enter a fault condition if the surface temperature exceeds 41 degrees Celsius

6.2	Finishe	Finished Device Drawing Number(s):			
	Initial:_	Date:			
6.3	Approv	al:			
		ative from QA must review and approve the specification information to ensure accuracy col. Quality Approval to Execute Testing:			
Si	anature:	Date:			
		Generation			
6		Describe the origin of the samples used. If new samples where created for this test, e any deviations, if applicable, that may impact testing:			

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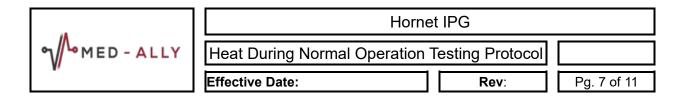
# 6.5

Oven or bath :		
Last Calibration:	Due:	
Temperature Recording Device:		<del></del>
Thermocouple Type(s):		
Last Calibration:	Due:	
Test Tank:		
DI Water PN:		
Lot Number:	Expires:	<del></del>
Timer:		
Last Calibration:	Due:	<del></del>
Notes:		
Initial: Date:		

Notes:

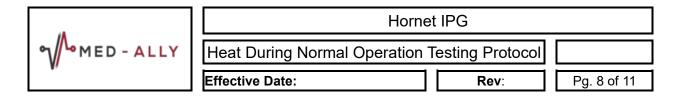
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intimate con	ce the thermocouples on the device(s) and photograph. Thermocouples should be in stact with the surface of the IPG, secured with Kapton tape. Photograph the device(s
	ocouples are attached, print, and attach the photographs to this protocol.
	uality representative shall review paperwork to ensure the drawing locations and shave been printed, identified, and attached to the protocol.
QA	Initial: Date:
stimulation v normal stim	ntify the Normal Modes of Operation Below (i.e. normal stimulation, normal with charging, charging only, normal stimulation with communication and charging, ulation with communication, etc). Print a copy of Appendix A: Operational Mode re Verification Form for each mode identified.
Mod	de 1:
Mod	de 2:
	de 3:
Mod	de 4:
Mod	de 5:
Mod	de 6:
	de 7:
Mod	de 8:
Note	

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6.5.6	Print	t a copy	of Appendix E	3: Temperatur	e Fau	ult Verifi	cation Form	1.
	Initia	al:	Date:			-		
6.5.7 consis			hermo-logger ent temperatu		e(s) u	ınder te	st. Ensure th	ne data provided is
			Date:			_		
6.5.8	Set t	the Over	n to 37C.					
6.5.9			Date:			_	oborgor oo	it is in proper range to
the de		e ille de	vice into the L	Ji vvater rank	i. Sec	ure ure	charger so	it is in proper range to
0.5.40			Date:					
	er, into	the ove		ermocouple p	robe	leads ex	kiting the ov	he device, water, and en passthru or through
			Date:			-		
Apper tempe of 1 he sampl	erature ndix A: erature our. At e. Pas	or bath Operation logged to the consisting indicate	temperature of onal Mode Te for each of the clusion of all s	of 37C. Once emperature Ve e applicable n samples and i emperature is	the Derifica nodes mode	I water tion For in the a	is at temper ms. Record appropriate , indicate Pa	to the ambient oven rature, complete the the Highest column after a minimunass or Fail for each highest temperature
NOTE	: Ensı	ure the c	data logger is	s on and reco	ordin	g tempe	erature data	a.
	Initia	al:	Date:			_		



6.5.12 Once all devices and operational modes have been completed, set the temperature of the oven or bath to 42 degrees Celsius. Complete the Appendix B form for Temperature Fault Verification. Ensure the device is communicating during the test, and ensure the data logger is recording in order to specify the fault temperature on the form. For tests involving more than once sample, the DI water must cool to below 41 degrees before starting subsequent devices.

Initial:	Date:	· · · · · · · · · · · · · · · · · · ·		
Notes:			 	
nitial:	Date:			



App	rovais		
7.1	Verify	testing results meet all applicable specif	ications
lr	nitial	Date	
7.2		ty Approval	
		Review Protocol	
7	7.2.2	Review Appendix A: Operational Mode	Temperature Verification Form
7	7.2.3	Review Appendix B: Temperature Fault	Verification Form
7	7.2.4	Review Appendix C: Additional Notes	
<u></u>	ianatur		Data
7 2	ignature Othor	e: Approval (If required):	Date:
1.3	Other	Approvai (ii required).	
S	ignatur	e:	Date:
7.4	Notes	e: s (if required):	
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Appendix	A. Opei	Mod	e- Recor	d High T	emn after	ation Forn 1 Hour O	neration		
Sample #	1	2	3	4	5	6	7	8	Pass/F ail
_									

Signature:	Date:	Page (	of
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Appendix B: Temperature Fault Verification Form

Sample #	Fault Temp.	Pass/Fail	Notes

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

Signature:	Date:	Page of