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
A	Operational Mode Temperature Verification Form
B	Temperature Fault Verification Form
C	Additional Notes Area (if required)

5 Definitions

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

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 **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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_____

_____

_____

Initial:_____ Date:_____

6.5 Heating Test:

6.5.1 Record the equipment and consumables designated for the test:

Oven or bath :_____

Last Calibration:_____Due:_____

Temperature Recording Device:_____

Thermocouple Type(s):_____

Last Calibration:_____Due:_____

Test Tank:_____

DI Water PN:_____

Lot Number:_____Expires:_____

Timer:_____

Last Calibration:_____Due:_____

Notes:_____

_____

_____

_____

_____

Initial:_____ Date:_____

6.5.2 Print a copy of the final device assembly. Mark the assembly with the thermocouple locations selected for the heat test. Below, justify why the locations were selected (i.e. closest proximity to batteries, high temp chips, front/back, etc.):

Notes:_____

_____

_____

_____

_____

Initial:_____ Date:_____

6.5.3 Place the thermocouples on the device(s) and photograph. Thermocouples should be in intimate contact with the surface of the IPG, secured with Kapton tape. Photograph the device(s) once thermocouples are attached, print, and attach the photographs to this protocol.

Initial:_____ Date:_____

6.5.4 A Quality representative shall review paperwork to ensure the drawing locations and photographs have been printed, identified, and attached to the protocol.

QA Initial:_____ Date:_____

6.5.5 Identify the Normal Modes of Operation Below (i.e. normal stimulation, normal stimulation with charging, charging only, normal stimulation with communication and charging, normal stimulation with communication, etc). Print a copy of Appendix A: Operational Mode Temperature Verification Form for each mode identified.

Mode 1:_____

Mode 2:_____

Mode 3:_____

Mode 4:_____

Mode 5:_____

Mode 6:_____

Mode 7:_____

Mode 8:_____

Notes:_____

_____

_____

_____

_____

Initial:_____ Date:_____

6.5.6 Print a copy of Appendix B: Temperature Fault Verification Form.

Initial:_____ Date:_____

6.5.7 Turn on the thermo-logger for the device(s) under test. Ensure the data provided is consistent with ambient temperature.

Initial:_____ Date:_____

6.5.8 Set the Oven to 37C.

Initial:_____ Date:_____

6.5.9 Place the device into the DI Water Tank. Secure the charger so it is in proper range to the device.

Initial:_____ Date:_____

6.5.10 Fill the DI Water Tank with Distilled Water. Place the tank, with the device, water, and charger, into the oven, with the thermocouple probe leads exiting the oven passthru or through the door in a manner that allows attachment to the thermo-logger.

Initial:_____ Date:_____

6.5.11 With the device and charger OFF, allow the DI water to stabilize to the ambient oven temperature or bath temperature of 37C. Once the DI water is at temperature, complete the Appendix A: Operational Mode Temperature Verification Forms. Record the Highest temperature logged for each of the applicable modes in the appropriate column after a minimum of 1 hour. At the conclusion of all samples and mode testing, indicate Pass or Fail for each sample. Pass indicates the high temperature is <41C. Fail indicates the highest temperature recorded is greater than or equal to 41C.

NOTE: Ensure the data logger is on and recording temperature data.

Initial:_____ 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:_____

_____

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_____

_____

Initial:_____ Date:_____

7 Approvals

7.1 Verify testing results meet all applicable specifications

Initial_____ Date_____

7.2 Quality Approval

7.2.1 Review Protocol

7.2.2 Review Appendix A: Operational Mode Temperature Verification Form

7.2.3 Review Appendix B: Temperature Fault Verification Form

7.2.4 Review Appendix C: Additional Notes

Signature:_____ Date:_____

7.3 Other Approval (If required):

Signature:_____ Date:_____

7.4 Notes (if required):

_____

_____

_____

_____

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_____

Appendix A: Operational Mode Temperature Verification Form

Sample #	Mode- Record High Temp after 1 Hour Operation								Pass/Fail
	1	2	3	4	5	6	7	8	

Signature:_____ Date:_____Page___ of____

Appendix B: Temperature Fault Verification Form

Sample #	Fault Temp.	Pass/Fail	Notes

Signature:_____ Date:_____Page___ of____

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

Signature:_____ Date:_____ Page___ of____