1 Purpose

This protocol prescribes methods and records results to ensure the Hornet IPG adheres to accelerated aging 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 the devices continue to meet standards and requirements for the anticipated lifecycle of the device, and forms to record testing results. Section 8, Approvals, is intended to be repeatedly completed as testing stages of accelerated aging or real time samples and functional testing is completed.

3 References

Document No.	Title
ISO 14708-1: 19-1	Implants for surgery – Active implantable medical devices – Part 1: General requirements for safety, marking and for information to be provided by the manufacturer
BS EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices, Part 1: Requirements for materials, sterile barrier systems, and packaging
ASTM F1980-16	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

4 Appendices

Appendix:	Title
A	Characterization of Material
B	Accelerated Aging Interval Record
C	Performance Test Requirements
D	Performance Testing Record
E	Serial Number Log
F	Real Time Aging Record
G	Testing Deviation Log
H	Additional Notes Area (if required)

5 Definitions

Abbreviation or Term	Definition
DVT	Design Verification Test
IPG	Implantable Pulse Generator
DUT	Device Under Test
T_{AA}	The elevated temperature at which the aging study is conducted, and it may be based on the estimated storage temperature, estimated usage temperature, or both
AAF	Accelerated Aging Factor; a correlation between the number of real time days to the number of simulated accelerated days, where 1 AAF = X RT days (reference calculations in the protocol for more information)
AAT	The length of time the accelerated aging is conducted
T_{RT}	Storage temperature of real-time aging (RT) samples that represent storage conditions
Q_{10}	An aging factor for 10℃ increase or decrease in temperature
T_m	Temperature at which a material melts
T_g	Glass transition temperature
T_α	Alpha temperature, heat distortion temperature
RT	Storage time of samples at ambient conditions
$RT_\#$	Number of real time days; desired real time shelf life duration or interval
$AAT_{RT\#}$	Number of Accelerated Aging days, representing (real time * AAF) days in an interval period
Morphology	Examples include glassy amorphous, semi-crystalline, highly crystalline, % crystallinity, size, shape, structure, etc.

6 Testing Protocol

6.1 Per the applicable standards, accelerated aging methods shall be used to determine any effects the passage of time may have on packaging components. Product requirement documents will establish the anticipated lifecycle of the sterlie packaging system, and be used as guidance for accelerated aging parameters. Record the following information and perform calculations to determine accelerated aging parameters:

6.1.1 The Hornet IPG PN: will be tested to simulate 2 years using accelerated aging.

6.1.2 List of Device Materials and Heat sensitive components:

Part Number: _____

Part Number: _____

Part Number: _____

Part Number: _____

Part Number:_____

Part Number: _____

Part Number: _____

Part Number: _____

Part Number: _____

Part Number: _____

Part Number:_____

Part Number: _____

Part Number: _____

Part Number: _____

Complete Appendix A, Characterization or Materials, for each part unique part number of the device.

Initial:_____ Date:_____

6.1.3 Long Term Storage Ambient Temperature* (T_{RT}): 37 ℃

6.1.4 Accelerated Aging Temperature* (T_{AA}) : 55 ℃

6.1.5 Q Factor* (Q_{10}): 2.0
*Use 2.0 unless otherwise specified

6.1.6 Calculate Accelerated Aging Factor. Where:
AAF = Accelerated Aging Factor
T_{AA} = Accelerated Aging Temperature
T_{RT} = Ambient storage Temperature
Q_{10} = Q Factor

$$AAF = Q_{10}^{[(TAA - TRT)/10]}$$

$AAF = 2.0^{[(55 \text{ minus } 37) \text{ divided by } 10)]}$
$AAF = 2.0^{[(18) \text{ divided by } 10)]}$
$AAF = 2.0^{[1.8]}$
AAF = 3.48 Days

6.1.7 Desired Real Time Intervals ($RT_{\#}$):

RT_1: 90 Days (3 months)
RT_2: 182 Days (6 months)
RT_3: 365 Days (12 Months)
RT_4: 730 Days (24 Months)
RT_5: 1095 Days (36 Months)
RT_6: 1460 Days (48 Months)
RT_7: 1825 Days (60 Months)

6.1.8 Accelerated Aging Time (AAT) for each Desired Real Time interval (Round to nearest whole number):

$RT_1 = 90$
$AAT_{RT1} = RT_1$ Days / AAF
AAT_{RT1} = 90 divided by 3.48
AAT_{RT1} = 26 Days

$RT_2 = 183$
$AAT_{RT2} = RT_2$ Days / AAF

AAT_{RT2} = 183 divided by 3.48
AAT_{RT2} = 53 Days

RT_3 = 365
AAT_{RT3} = RT_3 Days / AAF
AAT_{RT3} = 365 divided by 3.48
AAT_{RT3} = 105 Days

RT_4 = 730
AAT_{RT4} = RT_4 Days / AAF
AAT_{RT4} = 730 divided by 3.48
AAT_{RT4} = 210 Days

Print a copy of Appendix B, Accelerated Aging Interval Record, and complete the AAT information (top portion) for each desired interval required. Print an additional copy for RT_0, to establish baseline testing results.

Initial:_____ Date:_____

6.1.9 Performance Testing Requirements:
Complete Appendix C, Performance Test Requirements, to outline the tests to be performed by all accelerated and real time performance testing. Tests selected for evaluation should challenge the materials or device functionality that is most critical or most likely to fail as a result of aging.

Initial:_____ Date:_____

6.2 **Document the required number of RT samples below:**

Total Real Time Sample Number:_____

Complete a copy of Appendix F for all Reat Time Aging test intervals, top portion only.

Initial:_____ Date:_____

6.3 **Total Sample Number:**_____, as required per XXXX Hornet IPG and Charger Test Plan

6.4 **Finished Device Drawing Number(s):**_____

Initial:_____ **Date:**_____

6.5 **Approval:**

A representative from QA must review and approve the specification information to ensure accuracy of test protocol.

Quality Review Checklist:

Life-cycle Requirements Initial_____ Date:_____

Appendix A (Initial & Date on form) Qty:_____ Initial_____Date:_____

AAF Calculation Verification Initial_____ Date:_____

Desired RT Interval Verification Initial_____ Date:_____

$AAT_{RT\#}$ Calculation Verification Initial_____ Date:_____

Sample Number Verification Initial_____ Date:_____

Appendix B (Top Portion) Qty:_____ Initial_____Date:_____

Appendix C Performance Test Requirements Initial_____ Date:_____

Appendix F Real Time Aging Record (Top Portion) Initial_____ Date:_____

Notes:_____

_____

_____

_____

Quality Approval to Execute Testing:

Signature:_____ **Date:**_____

Due to duration of testing and costs, customer review and approval is required prior to starting Accelerated Aging. Customer Approval:

Print Name:_____

Position:_____

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. Include work order number if available.

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Initial:_____ Date:_____

6.7 **Sterilization**

6.7.1 Submit all samples for sterilization per standard procedure:

Work Instruction:_____

Shipping Date:_____

Initial:_____ Date:_____

6.7.2 Perform visual inspection on all samples for anomalies, damage, and paperwork completeness. Attach sterilization records to this protocol.

Post Sterilization Return Date:_____

Visual Inspection- Initial:_____ Date:_____

Paperwork Verification- QA Initial:_____Date:_____

6.8 **Equipment Information:**

Controlled Environment Chamber or Bath:_____

Temperature Controller:_____

Last Cal:_____ Cal Due:_____

Timer:_____

Last Cal:_____ Cal Due:_____

Thermal Logger:_____

Last Cal:_____ Cal Due:_____

Notes:_____

_____

_____

_____

Initial:_____ Date:_____

6.9 **Accelerated Aging and Real Time Testing:**

6.9.1 Complete Appendix D, Serial Number Log to designate devices for their intended testing purpose. Reference the Testing Protocol section for required sample numbers in each category.

Operator Initial:_____ Date:_____

6.9.2 Place all real time samples into storage location. Record the Start date, andticipated finsh date, and initial and date on all Appendix F, Real time Aging records to record real time aging initiation.

Operator Initial:_____ Date:_____

6.9.3 Place all accelerated aging samples into the BATH 0.9% sodium chlorine, ensuring the temperature setpoint matches requirements. Record the Actual Start Date and Anticipated Finish Date for all Appendix B, Accelerated Aging Interval Record for all AATRT# forms to record accelerated aging initiation. Ensure thermologger is recording data at a rate >= 1 sample per minute.

Solution Part Number:_____

Solution Lot Number:_____

Solution Expiration Date:_____

Operator Initial:_____ Date:_____

6.9.4 RT_0 devices, as designated by Appendix E, Serial Number Log, may be tested immediately per requirements of Appendix C, Performance Testing Requirements, and recorded on the form in Appendix D, Performance Testing Record. Attach any reports generated by required testing to Appendix D, and submit the forms to QA for review upon completion.

Operator Initial:_____ Date:_____

6.9.5 Enter the Next Anticipated completion dates for $AAT_{RT\#}$ and $RT_{\#}$. Upon completion of required durations, review data logs to ensure accelerated aging devices have completed the required time period. Print an attach verification data to this protocol as it becomes available. Complete copies of Appendix D, Performance Testing Record for each batch of parts that meet accelerated or real time aging required durations.

In the event of power disruptions or data loss, complete Appendix G, Testing Deviation Record, to amend the duration requirements and change the anticipated completion dates.

Note: An NCR is NOT required if time is extended equal to the power out period or period of data loss if the deviation form is completed and attached, and no risk from the adverse event is expected to impact device performance.

The steps in this section shall be repeated until all aging durations are completed, and reviewed in the Approvals section.

7 Approvals –

Note: This approval page is intended to be completed for each Accelerated Aging or Real time data set. Release the protocol and up-rev with each completed aging stage.

7.1 Describe the functional testing stage being completed (AAT=RTx; Rtx, Etc):

_____

_____

7.2 Verify testing results meet drawing requirements and test standards

Initial_____ Date_____

7.3 Quality Approval

- 7.3.1 Review Protocol Completeness
- 7.3.2 Review Appendix A: Characterization of Material
- 7.3.3 Review Appendix B: Accelerated Aging Interval Record
- 7.3.4 Review Appendix C: Performance Testing Requirements
- 7.3.5 Review Appendix D: Performance Testing Record
- 7.3.6 Review Appendix E: Serial Number Log
- 7.3.7 Review Appendix F: Real Time Aging Record
- 7.3.8 Review Appendix G: Testing Deviation Record
- 7.3.9 Review Appendix H: Additional Notes
- 7.3.10 Ensure records support all required real time and accelerated aging durations.

Signature:_____ Date:_____

7.4 Other Approval (If required):

Signature:_____ Date:_____

7.5 Notes (if required):

_____

_____

_____

_____

Appendix A: Characterization of Material

Part Number:_____

Part Description:_____

Composition:_____

Morphology:_____

T_m=_____℃ T_g=_____℃ T_α=_____℃

Additive, processing agents, catalysts, lubricants, residual solvents, corrosive gasses, and fillers, or other notes:

_____

_____

_____

_____

_____

_____

_____

_____

Suggested Max Temperature:_____℃

Signature:_____ Date:_____

QA Initial:_____ Date:_____

Appendix B: Accelerated Aging Interval Record

Finished Assembly Drawing Number:_____

$AAT_{RT\#}$:_____ Real Time
Duration:_____days

Accelerated Aging Time:_____days Sample Number:_____

Temperature Set Point:_____

Print Name:_____

Signature:_____ Date:_____

Actual Start Date:_____ Initial:_____ Date:_____

Anticipated Finish Date:_____

Deviations:

_____

Notes:

_____

_____

Finish Date:_____ Sample Number:_____

Attach Thermologger Data (Check): ____ Total Accelerated Aging Time:_____

Minimum Duration at Accelerated Temperature Verified (check): ____

Print Name:_____

Signature:_____ Date:_____

Appendix C: Performance Testing Requirements

Visual Inspection Requirements:

_____

_____

_____

_____

_____

Functional Testing Requirements:

_____

_____

_____

_____

_____

Bench Testing Requirements:

_____

_____

_____

_____

_____

Operator Signature:_____ Date:_____

Quality Signature:_____ Date:_____Page___ of____

Appendix D: Performance Testing Record

Serial Number	Visual Inspection Pass/ NCR#	Functional Inspection Pass/ NCR#	Bench Testing Pass/ NCR#	Notes:

Operator Signature:_____ Date:_____

Quality Signature:_____ Date:_____Page___ of____

Appendix E: Serial Number Log

Serial Number	Select One		RT#	Testing Duration (Days)	Start Date
	Accelerated Aging	Real Time Aging			

Operator Signature:_____ Date:_____

Quality Signature:_____ Date:_____Page___ of____

Appendix F: Real-Time Aging Record

Finished Assembly Drawing Number:_____

RT#:_____Duration:_____days

Sample Number:_____ Ambient Start Temperature: _____

Print Name:_____

Signature:_____Date:_____

Start Date:_____Anticipated Finish Date:_____

Initial:_____Date:_____

Deviations:

_____

_____

Notes:

_____

_____

_____

Ambient Finish Temperature:_____

Actual Finish Date:_____ Sample Number:_____

Total Time Elapsed:_____ days

Print Name:_____

Signature:_____Date:_____

Appendix G: Testing Deviation Record

Date of Deviation:_____

Cause of Deviation:_____

_____

_____

Current RT#:_____

End of Deviation Date:_____

Prior anticipated RT# Aging Completion Date:_____

New anticipated RT# Aging Completion Date:_____

NCR:_____ if applicable*
*NCR is not required if the only impact is completion extension.

Engineer Name:_____

Engineer Signature:_____ Date:_____

QA Representative Name:_____

QA Signature:_____Date:_____

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

Signature:_____ Date:_____ Page___ of____