

	Design Verification Report Summary – Electrodes	Doc. Number	Rev.
		NNP-DVES-0002	v1

NNP-DVES-0002 - Design Verification Report Summary – Electrodes

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1.0 Document Purpose

This report summarizes the activities and results of design verification performed on the COSMIIC system against its product requirements.

2.0 Document Scope

This design verification summary report applies to the Electrodes. This report addresses verification results for the design input requirements that are defined in *NNP-REQ-0002 – Product Requirements Specification – Electrodes*.

3.0 Background

This is the initial design verification activity for the Electrodes as they are to be released open source.

4.0 Definitions

Term	Definition
AIMD	Active Implantable Medical Device
DFT	Drawn-Filled Tube
Breakout Force	Definition used by BalSeal Engineering Inc. It is the maximum force in the first 20% of the ID Gage travel into the Balseal.
Insertion Force	Force required to insert a straight circular pin with chamfered end into the BalSeal. For grooved pin insertion force denotes the force required to get the BalSeal off the groove in one direction.
Extraction Force	Force required to get the BalSeal off the groove in the opposite direction.
Running Force	Force required to move the BalSeal on a circular pin.
Balseal ID	Balseal spring inner diameter. It is measured from the SEM image of the Balseal by inscribing a circle that touches most part of the spring.

5.0 Verification Approach

5.1 General Verification Approach

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Electrodes were put through four tests for stretching, crushing, flexing, and torquing. These are detailed in the table below. This combination shows the physical viability of the Electrodes for use in the COSMIIC System. The Interconnect and Balseals were studied on the effects of different parameters to establish reliable and consistent seal force results.

Document Number	Name	Description
NNP-DVEP-0006	Electrode Cable Stretch Test	Test articles are stretched to 120% of the initial installed length for 1.2×10^6 cycles.
NNP-DVEP-0007	Electrode Cable Crush Test	Test articles crushed by a force of 1.2N delivered over a 1cmx2mm bar for 1.2×10^5 cycles.
NNP-DVEP-0008	Electrode Cable Flex Test	Test articles are bent over a 3mm radius rod at an angle of 140° for 1.2×10^6 cycles.
NNP-DVEP-0009	Electrode Cable Torsion Test	Test articles are twisted at a rate of 36° of rotation per linear cm of separation about the axis of separation for 6×10^5 cycles.
NNP-DVEP-0011	BalSeal Interconnect Testing	To study the effect of Balseal design parameters and loading conditions on the BalSeal insertion, extraction, and running forces.

5.2 Requirements Addressed

This Design Verification Summary demonstrates the satisfaction of each of the requirements defined in *NNP-REQ-0002 – Product Requirements Specification Electrodes*.

5.3 Devices Under Test

The test samples used for this verification activities are itemized below:

Sample Type	Specimen ID	Part Number
316LVM – 2 Filar	S2-02	NNP-DWG-140-012-002
		NNP-DWG-140-012-003
316LVM – 2 Filar	S2-03	NNP-DWG-140-012-002

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		NNP-DWG-140-012-003
316LVM – 2 Filar	S2-04	NNP-DWG-140-012-002
		NNP-DWG-140-012-003
316LVM – 2 Filar	S2-05	NNP-DWG-140-012-002
		NNP-DWG-140-012-003

5.4 Sample Size Rationale

The sample size is four (4) Electrode Cable bodies. The test result is binary (pass/fail) for each test sample. A sample size of 4 was deemed sufficient primarily due to the extensive time required for each test cycle, with hundreds of thousands of cycles needed per sample, each taking a few seconds. This results in several days of continuous testing per sample, meaning that running four samples on a single fixture spans a few weeks. Given the early development phase of the project, limited resources, and budget constraints, it was essential to balance thorough testing with the need to progress on multiple fronts. Contracting external experts in materials science further justified the decision to limit the sample size to four, as the associated costs and the high expense of the testing fixture necessitated a practical approach. Thus, four samples provided adequate data to inform decisions and allow the project to advance efficiently.

6.0 Acceptance Criteria

The acceptance criteria for each requirement are defined in the approved verification protocols used in this verification activity. All the acceptance criteria must be met for the overall result to be considered passing. The acceptance criterion for the mechanical tests were:

- No visual damage or fracture of the cable can be seen through the objective lens of the microscope while moving them slowly.
- The DC resistance per unit length of the cable must not increase by more than 100% from the initial pre-test values. Any cable exceeding this threshold will be considered a failure.
- The impedance of the cable must not decrease by more than 20% between pre-test and post-test measurements. Any cable with an impedance reduction beyond this limit will be deemed to have an insulating failure.

7.0 Deviations

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There were no deviations to the design verification plan.

8.0 Results and Analysis

8.1 Verification Results

A summary of the results on a protocol/report basis is provided in the table below. For each protocol-specific report, the number of requirements covered is listed and the overall pass/fail result for that report. The raw data, testing details and summary statistics for quantitative data, where applicable, are available in the referenced reports.

Protocol	Report	Requirement Count	Test Result
NNP-DVEP-0006 – Electrode Cable Stretch Test	NNP-DVER-0006 – Electrode Cable Stretch Test	1	PASS
NNP-DVEP-0007 – Electrode Cable Crush Test	NNP-DVER-0007 – Electrode Cable Crush Test	1	PASS
NNP-DVEP-0008 – Electrode Cable Flex Test	NNP-DVER-0008 – Electrode Cable Flex Test	1	PASS
NNP-DVEP-0009 – Electrode Cable Torque Test	NNP-DVER-0009 – Electrode Cable Torque Test	1	PASS
NNP-DVEP-0010 – Electrode Cable Post-Test Evaluations	NNP-DVER-0010 – Electrode Cable Post-Test Evaluations	4	PASS
NNP-DVEP-0011 – BalSeal Interconnect Testing	NNP-DVER-0011 – Interconnect, Balseals	4	PASS

8.2 Verification Findings

All samples passed testing for the 316LVM – 2 Filar sample type, as well as the visual inspection.

9.0 Conclusion

The Electrode Cable was verified to meet the predetermined acceptance criteria for the requirements defined in *NNP-REQ-0002 – Product Requirements Specification – Electrodes*.

10.0 References

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Document Identifier	Title
NNP-REQ-0002	Product Requirements Specification – Electrodes
NNP-DVEP-0006	Electrode Cable Stretch Test
NNP-DVER-0006	Electrode Cable Stretch Test
NNP-DVEP-0007	Electrode Cable Crush Test
NNP-DVER-0007	Electrode Cable Crush Test
NNP-DVEP-0008	Electrode Cable Flex Test
NNP-DVER-0008	Electrode Cable Flex Test
NNP-DVEP-0009	Electrode Cable Torque Test
NNP-DVER-0009	Electrode Cable Torque Test
NNP-DVEP-0010	Electrode Cable Post-Test Evaluations
NNP-DVER-0010	Electrode Cable Post-Test Evaluations
NNP-DVEP-0011	BalSeal Interconnect Testing
NNP-DVER-0011	Interconnect, Balseals
NNP-DWG-140-012-002	Cable Body, Insulated SS Filars, Red/Clear
NNP-DWG-140-012-003	Cable Body, Insulated SS Filars, Green/Clear

11.0 Revision History

Revision	Summary of Changes	Date	Author
v1	First version of document	8/30/2024	D. Romano