
	Design Verification Report - Electrode Cable Flex Test	Doc. Number	Rev.
		NNP-DVER-0008	v1

NNP-DVER-0008 - Design Verification Report – Electrode Cable Flex Test

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1.0 Document Purpose

This report documents design verification of the COSMIIC system against its reliability requirements. This verification activity was conducted in accordance with NNP-DEVP-0008 – Design Verification Protocol - Electrode Cable Flex Test.

2.0 Document Scope

This report addresses verification of the COSMIIC system against the reliability requirements that are defined in NNP-REQ-0002 – Product Requirements Specification – Electrodes.

This includes the following cables:


Cable	Part Number
Cable Body, Insulated SS Filars, Red/Clear	NNP-DWG-140-012-002
Cable Body, Insulated SS Filars, Green/Clear	NNP-DWG-140-012-003

3.0 Background

Initial design verification of the electrode cables against its reliability requirements was conducted to verify against NNP-REQ-0002 for the IDE submission of the COSMIIC device.

4.0 Definitions

Terms used in this protocol are defined in the applicable requirements specification(s) and standards, where referenced.

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5.0 Requirements Addressed


This protocol addresses the requirement listed below from NNP-REQ-0002 – Product Requirements Specification – Electrodes. The Requirement Text is for reference only; the listed Product Requirement Specification document is the definitive source for requirement content.

Req ID	Requirement Text
EL.7.3	The Electrode shall remain functional during and after 1.2×10^6 cycles of bending (wrapping) over a rod of 3mm radius with an angle of bend (wrap) of at least 140°.

6.0 Verification by Analysis

All tests were conducted using EnduraTEC TestBench (Bose Corporation, Minnetonka, MN) equipped with two pneumatic linear actuators and one electromagnetic torsion actuator. All tests were conducted under room temperature (nominally 22°C) laboratory conditions. Before mechanical testing, each sample was prepared for testing and connected to a Fluke 8711 True RMS multimeter to measure electrical resistance with resolution of 0.1W. Impedance of the sample was measured using the Electrochemical Impedance Spectroscopy technique. A Gamry PC4/FAS1 Femtostat with current detection resolution of 1pA was utilized to detect damage to the cable insulation layer. Each sample was placed in an electrochemical cell with a test solution of physiological saline solution of 0.9wt% NaCl. An AC voltage of 1V was applied to each filar of the test sample with frequency range varying from 100kHz to 100mHz. Impedance of the cable and phase angle between response current and applied voltage were recorded. The sample was then mounted between two pin vise grips with an exposed sample length of 45mm between the grips.

Flex testing was performed on the sample mounted between pin vise grips as follows. A schematic diagram for this test setup is shown in Figure 1.

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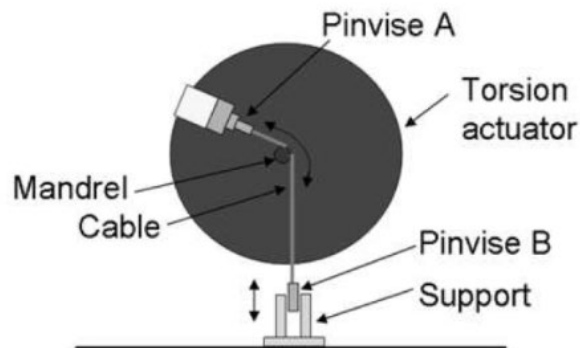


Figure 1. Flex Test - Schematic

6.1 General Approach


Verification was accomplished using test methods and inspection. Testing was used to confirm the Electrode Cable meets the strength and durability requirements. Inspection was used to verify there was no damage or fracture to the insulating tubing of the cable after testing.

6.2 Sample Size

The sample size was four (4) Electrode Cable bodies. The test result was 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 resulted in several days of continuous testing per sample, meaning that running four samples on a single fixture spanned 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.

6.3 Test Article

The test samples were in a work in progress state; it was the finished cable body before the final assembly with the interconnect and electrodes.

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6.4 Test Facility, Dates and Personnel

Verification was conducted in the Case Western Reserve University engineering laboratory under room temperature ($22\pm 2^{\circ}\text{C}$) conditions.

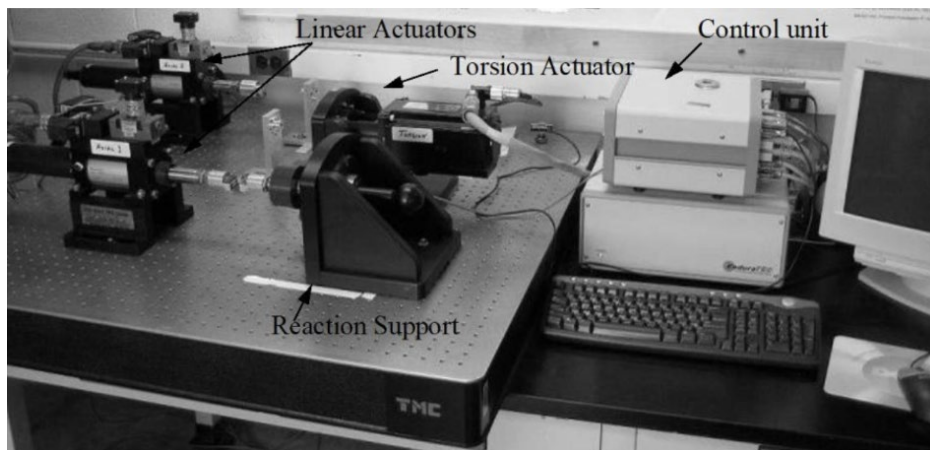


Figure 2. EnduraTEC TestBench with actuators and control unit.

6.5 Equipment and Materials

All tests were conducted using EnduraTEC TestBench (Bose Corporation, Minnetonka, MN) equipped with two pneumatic linear actuators and one electromagnetic torsion actuator. After testing, each cable was examined under an Olympus DP20 (Olympus America Inc, Center Valley, PA) optical microscope at 45x magnification.


6.6 Acceptance Criteria

The acceptance criterion for the mechanical flex test was:

- No visual damage or fracture of the cable can be seen through the objective lens of the microscope while moving them slowly.

7.0 Deviations

There were no deviations to the protocol.

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8.0 Test Results

Sample ID	Sample Type	Visual Inspection Pass/Fail	Notes
50-1	316LVM, 2-filar	NA	Apparatus failed, test invalid
50-2		Pass	
50-3		Pass	
50-4		Pass	
50-5		Pass	

For the 316LVM 2-filar sample type, one test iteration experienced an apparatus failure and thus an additional sample was tested. All additional 4 test samples passed testing.

9.0 Conclusion

The COSMIIC system components, part numbers NNP-DWG-140-012-002 and NNP-DWG-140-012-003, successfully satisfied the reliability requirements (REQ ID EL.7.3) defined in NNP-REQ-0002 - Product Requirements Specification – Electrodes.

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10.0 References

Document Identifier	Title
NNP-DVEP-0008	Design Verification Protocol – Electrode Cable Flex Test
NNP-REQ-0002	Product Requirements Specification – Electrodes
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.	7/19/2024	J. Daghestani