**NNP-DVER-0003 - Design Verification Report – Network Cable Flex Test**

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1. **Document Purpose**

This report documents design verification of the COSMIIC system against its functional requirements. This verification activity was conducted in accordance with NNP-DEVP-0003 – Design Verification Protocol - Network Cable Flex Test.

1. **Document Scope**

This report addresses verification of the COSMIIC system against the functional requirements that are defined in NNP-REQ-0001 – Product Requirements Specification – Network Cable.

This includes the following cables:

|  |  |
| --- | --- |
| **Cable** | **Part Number** |
| Cable Body, Insulated DFT Filars, Blue/Clear | NNP-DWG-140-012-001 |
| Cable Body, Insulated SS Filars, Red/Clear | NNP-DWG-140-012-002 |
| Cable Body, Insulated SS Filars, Green/Clear | NNP-DWG-140-012-003 |

1. **Background**

Initial design verification of the network cables against its functional requirements was conducted to verify against NNP-REQ-0001 for the IDE submission of the COSMIIC device.

1. **Definitions**

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

1. **Requirements Addressed**

This protocol addresses the requirement listed below from NNP-REQ-001 – Product Requirements Specification – Network Cable. The Requirement Text is for reference only; the listed Product Requirement Specification document is the definitive source for requirement content.

|  |  |
| --- | --- |
| Req ID | Requirement Text |
| 1.0 | Cables crossing joints or regions of great tissue motion shall be functional during and after 1.2 x 106 cycles of bending (wrapping) over a rod of 3mm radius. The angle of bend (wrap) shall be at least 140°. This is a requirement for flexing life; it is not a requirement for wear or abrasion of the cable against the rod. |

1. **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 pinvise grips with an exposed sample length of 45mm between the grips.

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

Diagram of a cable with text

Description automatically generated with medium confidence

**Figure 1.** Flex Test - Schematic

* 1. **General Approach**

Verification was accomplished using test methods and inspection. Testing was used to confirm the Network 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.

* 1. **Sample Size**

The sample size was four (4) Network 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.

* 1. **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.

* 1. **Test Facility, Dates and Personnel**

Verification was conducted in the Case Western Reserve University engineering laboratory under room temperature (22±2°C) conditions.

A close-up of a machine

Description automatically generated

**Figure 2.** EnduraTEC TestBench with actuators and control unit.

* 1. **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.

* 1. **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.

1. **Deviations**

There were no deviations to the protocol.

1. **Test Results**

|  |  |  |
| --- | --- | --- |
| Sample ID | Visual Inspection Pass/Fail | Notes |
| S2 | Pass | SS Cable |
| S4 | Pass | SS Cable |
| D2 | Pass | DFT Cable |
| D4 | Pass | DFT Cable |

All 4 tested samples passed visual inspection per the acceptance criteria listed above.

1. **Conclusion**

The COSMIIC system components, part numbers NNP-DWG-140-012-001, NNP-DWG-140-012-002, and NNP-DWG-140-012-003, successfully satisfied the functional requirements (REQ ID 1.0) defined in NNP-REQ-0001 - Product Requirements Specification – Network Cable.

1. **References**

|  |  |
| --- | --- |
| **Document Identifier** | **Title** |
| NNP-DVEP-0003 | Design Verification Protocol – Network Cable Flex Test |
| NNP-REQ-0001 | Product Requirements Specification – Network Cable |
| NNP-DWG-140-012-001 | Cable Body, Insulated DFT Filars, Blue/Clear |
| NNP-DWG-140-012-002 | Cable Body, Insulated SS Filars, Red/Clear |
| NNP-DWG-140-012-003 | Cable Body, Insulated SS Filars, Green/Clear |

1. **Revision History**

|  |  |  |  |
| --- | --- | --- | --- |
| **Revision** | **Summary of Changes** | **Date** | **Author** |
| v1 | First version of document. | 7/12/2024 | J. Daghstani |

1. **Approvals**

See Document Change Request log for approvals.