smiths interconnect

Qualification Test Report

D SERIES

Qualification of D04 Plug and Receptacle

Revision B
2nd March 2023

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1. Scope

The purpose of this document is to define the test samples, test sequence, and test methods required for characterization testing of D04 plug and receptacle.

2. Order of Precedence

In case of a conflict between the text of this document and the applicable referenced documents, the text of this document shall take precedence.

3. Description of Test Articles

The initial characterization testing will consist of 3 mated pairs for testing in support of each Sub-Group A through D, for Group 1. Group 1 Test Articles are assembled per Table 1. Group 3 Test Articles are assembled per Table 2.

All test samples utilized in the characterization tests will be assembled mated pair connectors, described in Table 1.

Table 1: Group 1 - Description of Test Articles (Autoclave)

Parts for Group 1 - Autoclave				
Part Number	**Identification**	**Group**	**Subgroup**	**Description/Prep**
P-ZMDS082-001	DUT1-1A DUT2-1A DUT3-1A	1	A	D04 Receptacle Body, fully populated with PC Pins
P-ZMDS000-001/002		1	A	D04- Plug Body/Plug SR/Overmold preassembled with (#26 Teflon Wire) min 2ft crimped and installed in connector opposite end tinned, fully populated, odd pins – white wires, even pins - blk wires
P-ZMDS082-001	DUT1-1B DUT2-1B DUT3-1B	1	B	D04 Receptacle Body, fully populated with PC Pins and soldered to LLCR Ground Fixture Board
P-ZMDS000-001/002		1	B	D04- Plug Body/Plug SR, fully populated with pins, 10 being prewired with 24" length and size #30 white Teflon Wire, 10 outer pins (1,5,10,22,33,45,56,68,77,80, assembled with 2 parallel wires crimped together in each respective pin, opposite end stripped and tinned (labeled with contact pin #s)
P-ZMDS082-001	DUT1-1C DUT2-1C DUT3-1C	1	C	D04 Receptacle Body, assembled with required contacts
P-ZMDS000-001/002		1	C	D04- Plug Body/Plug SR, fully populated with pins using Iso-sese Cable with 82 of the 110 crimped to 82 pins 6' long with all wires pigtailed back 6", stripped and tinned with labels on the pigtail ends corresponding to each pin#. (connector end shall be assembly/Strain relief per released prints)
P-ZMDS082-001	DUT1-1D DUT2-1D DUT3-1D	1	D	D04 Receptacle Body, unassembled with required contacts installed during test
P-ZMDS000-001/002		1	D	D04- Plug Body, unassembled with required contacts installed during test

Table 2: Group 3 – Description of Test Articles

Parts for Group 3				
Part Number	**Identification**	**Group**	**Subgroup**	**Description/Prep**
YPN004-010H	DUT1-3A-26,28,30 DUT2-3A-26,28,30 DUT3-3A-26,28,30 DUT4-3A-26,28,30 DUT5-3A-26,28,30	2	A	D04- Plug BodyContact Pin , 5 samples each of 28 AWG and 30 AWG teflon wire 24" long crimped per specification with wire labels applied identifying the DUT #

4. Standard Ambient Test Conditions

All tests and examinations specified by this characterization test procedure will be continued under any combination of conditions within the ranges stated in this paragraph, unless specified otherwise.

Temperature: 15°C to 35°C
Relative Humidity: 25% to 75%
Barometric Pressure: 860 hPa to 1060 hPa (86 kPa to 106 kPa)

5. References

Medical

ASTM-F 1980-07	Accelerated Aging of Sterile Barrier Systems for Medical Devices Including Environmental Classifications

Electronic Industries Alliance (EIA)

EIA-364-05	Contact Insert & Extraction forces
EIA-364-08	Crimp Tensile Strength Test Procedure for Electrical Connectors
EIA-364-09	Durability Test Procedure for Electrical Connectors and Sockets
EIA-364-13	Mating and Unmating Force Test Procedure for Electrical Connectors and Sockets
EIA-364-18	Visual and Dimensional Inspection Test Procedure for Electrical Connectors and Sockets
EIA-364-20	Withstanding Voltage Test Procedure for Electrical Connectors, Sockets and Coaxial Contacts
EIA-364-21	Insulation Resistance Test Procedure for Electrical Connectors, Sockets and Coaxial Contacts
EIA-364-23	Low Level Contact Resistance Test Procedure for Electrical Connectors and Sockets
EIA-364-42	Impact Test Procedure for Electrical Connectors
EIA-364-70	Temperature Rise Versus Current Test Procedure for Electrical Connectors and Sockets

ANSI/AAMI

AAMI-EC53	ECG Trunk Cables and Patient Lead Wires

Smiths Interconnect

ANSI/NCSL Z540.3-2006	Requirements for the Calibration of Measuring and Test Equipment
QMM 400A	Smiths Interconnect Quality Assurance Manual

6. Test Equipment and Facilities

6.1 Test Equipment

Table 3: Test Equipment

Type	Mfr & Model #	I.D. #
Dielectric Tester	HypotUltra 7800	35-901
Sourcemeter	Keithley 2410-C	35-909
Power Supply	Kepco ABC 10-10DM	35-908
Test Stand	Lloyd LFPlus	10-469
High Current Tester	Smiths Interconnect R3D3	35-908
Life Cycle Tester	Smiths Interconnect LCT4	08-0731

Table 4: Fixtures

Description	P/N
999-1033638	D04 Receptacle LLCR Ground Plane Bd
999-1034559	D04 Receptacle Ground Plane Bd Holding Fixture
999-1034560	D04 Plug Body Durability/Mating Holding Fixture
999-1034561	D04 Plug Body Bend/Flex Holding Fixture

6.2 Facilities

Testing was performed at:

Smiths Interconnect
5101 Richland Avenue
Kansas City, KS 66106
United States

7 Calibration

All test equipment used in the performance of the tests required herein shall be calibrated in accordance with ANSI/NCSL Z540-1-1994. Records of all equipment shall be maintained in accordance with ANSI/NCSL Z540-1-1994 and made available for review. Unless otherwise specified, Smiths Interconnect Quality Assurance will verify that all test data and collection methods are accurate and reliable.

8 Executive Summary

Testing was performed in accordance with Smiths Interconnect test plan QTP 2022-07-032 Rev C.

Durability with LLCR Measurements:
Measurements on DUT1-1B at cycle numbers 500 and 1,000 are invalid due to a bug in the LCT software that measured those samples when an insufficient stimulus of 10mA was inadvertently used instead of 100mA.

Post-Durability Mating/Unmating:
The requirement for mating force is ≤ 8.5 lbf. DUT3-1B measured a mating force of 9.00 lbf.

Crimp Tensile Strength Test:
The test requirement was for 26, 28 and 30 AWG wires to undergo crimp tensile strength tests. During preparation of parts, it was found that 26 AWG wire did not fit into the crimp contacts so this size wire was not included in the test. The datasheet shows individual failures for 26 AWG but the overall datasheet shows a passing test.

9 Test Sequence

The characterization test requirements and test sequence are shown in Table 5.

Table 5: Test Sequence

Test Procedure	Paragraph Reference	Subgroups	Pass/Fail Criteria	Results
Group 1 Initial Baseline Testing **Pre-Accelerated Aging and Sterilization**	**Paragraph Reference**	**1A, 1B, 1C, 1D**	**Pass/Fail Criteria**	
Visual Inspection	10.1	All	EIA-364-18, Pass Visual & Dimensional Requirements	Pass
Dielectric Withstanding Voltage	10.2	1A	EIA-364-20, 1000V, 5mA max leakage current	Pass
Insulation Resistance	10.3	1A	EIA-364-21, 500VDC, 5,000MΩ min	Pass
Low Level Contact Resistance	10.4	1B	EIA-364-23, At contact interface ≤ 10 mΩ	Pass
Sterilization Group 1 (Sample Groups 1A,1B,1C,1D)	**Paragraph Reference**	**Subgroups**	**Pass/Fail Criteria**	
ETO 2 cycles	10.5	1A1B,1C, 1D	N/A	Pass
Accelerated Aging	10.6	1A1B,1C, 1D	3-year equivalent at 90°C, 6.9 days	Pass
Chemical Wipe down-Caviwipes-	10.7	1A1B,1C, 1D	N/A	Pass
Autoclave 20 cycles total	10.8	1A,1B,1C, 1D	N/A	Pass
Post Sterilization **Group 1 (Sample Groups 1A,1B,)**	**Paragraph Reference**	**Subgroups**	**Pass/Fail Criteria**	
Post Sterilization-Dielectric Withstanding Voltage	10.9	1A	EIA-364-20, 1000V, 5mA max leakage current	Pass
Post Sterilization-Insulation Resistance	10.10	1A	EIA-364-21, >5,000 MΩ @ 500 VDC.	Pass
Post Sterilization - Low Level Contact Resistance	10.11	1B	EIA-364-23, At contact interface ≤ 10 mΩ	Pass
Group 1 (Subgroup 1B)	**Paragraph Reference**	**Subgroups**	**Pass/Fail Criteria**	
Pre-Durability Connector Mating/Unmating	10.12	1B	EIA-364-13, Mating ≤ 8.5 lbf, Unmating ≤ 7 lbf	Pass
Connector Durability At cycles; 0; .5k; 1.0k; 5k;10k	10.13	1B	EIA-364-09, 12 lbf insertion, 11 lbf extraction	Pass

Low Level Contact Resistance At cycles; 0; .5k; 1.0k; 5k;10k	10.14	1B	EIA-364-23, At contact interface ≤ 10 mΩ	Pass
Post-Durability Mating/Un-mating	10.15	1B	EIA-364-13, Mating ≤ 8.5 lbf, Unmating ≤ 7 lbf	Pass
Latch Retention Forces	10.16	1B	7 lbf minimum	Pass
Group 1 (Subgroup 1C)	**Paragraph Reference**	**Subgroups**	**Pass/Fail Criteria**	
Pre-Bend-Flex Testing Baseline Cable Resistance	10.17	1C	EIA-364-23, Characterization baseline resistance	Pass
Pre-Bend-Flex Testing - Dielectric Withstanding Voltage	10.18	1C	EIA-364-20, 1000V, 5mA max leakage current	Pass
Pre-Bend-Flex Testing - Insulation Resistance	10.19	1C	EIA-364-21, >5,000 MΩ @ 500 VDC	Pass
Bend Flex	10.20	1C	AAMI-EC53	Pass
Post-Bend-Flex Testing Cable Resistance	10.21	1C	EIA-364-23, ≤ 50% increase from baseline	Pass
Post-Bend-Flex Testing - Dielectric Withstanding Voltage	10.22	1C	EIA-364-20, 1000V, 5mA max leakage current	Pass
Post-Bend-Flex Testing - Insulation Resistance	10.23	1C	EIA-364-21, >5,000 MΩ @ 500 VDC	Pass
Group 1 (Sample Groups 1D)	**Paragraph Reference**	**Subgroups**	**Pass/Fail Criteria**	
Contact Insertion /Extraction Forces	10.24	1D	EIA-364-05B 10 contacts, Insertion ≤ 3lb, Extraction ≤ 10lbf	Pass
Heat Rise Test (1 contact activated) - 0.20A Increments until 70°C heat rise max	10.25	1D	EIA-364-70, Product characterization	Pass
Group 2 (Sample Group 2)	**Paragraph Reference**	**Subgroups**	**Pass/Fail Criteria**	
Crimp Tensile	10.26	3A	EIA-364-08B #28 > 1 lbf, #30 > 0.8 lbf	Pass

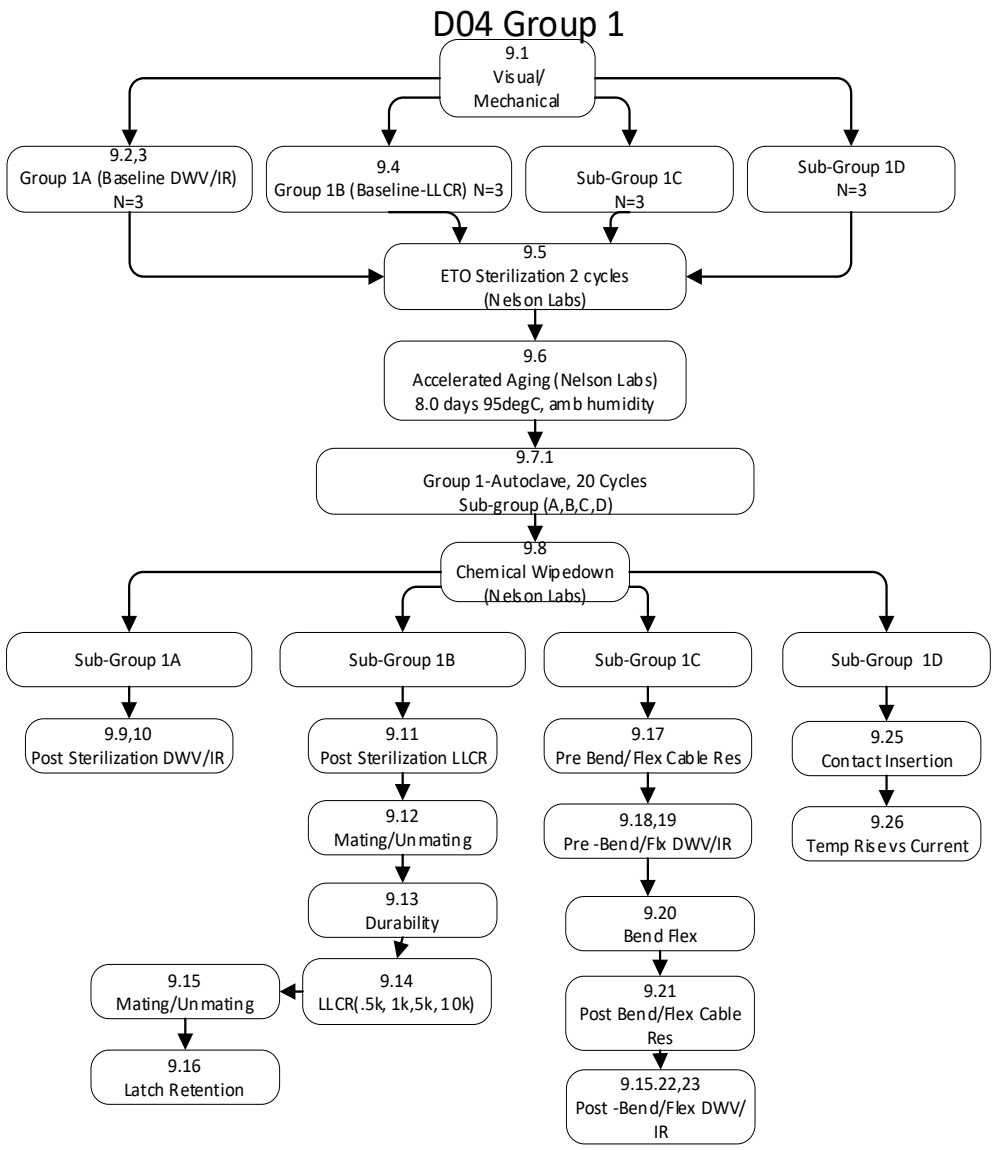

Figure 1: Test Flow – Group 1

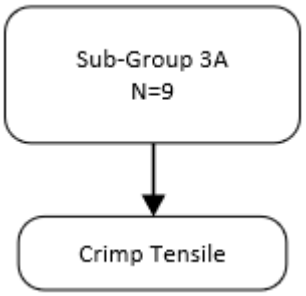

Figure 2: Test Flow – Group 3

10 Test Procedures & Results

10.1 Visual and Mechanical

With reference to EIA-364-18, connector assemblies and/or subassemblies shall be examined as specified in part drawings and shall meet the requirements specified.

Scope:
Following design intent, connectors will be subjected to Smiths Interconnect first article inspection process.

Sample size:

1. Pin contacts (15) - Pin contacts will be used for the crimp tensile test
2. Plug connectors (24)
3. Receptacle connectors (24)

Requirement:
Connectors must meet drawing requirements.

Pass/Fail: Pass

10.2 Dielectric Withstanding Voltage

Requirements:
Measurements shall be performed and recorded with reference to EIA-364-20E, Test Method B. A test voltage of 1000 VDC shall be applied between most closely spaced contacts and between connector shell. The test samples shall be a plug and receptacle mated together. The test voltage shall be raised at a rate of approximately 500 volts per second. The test voltage shall be maintained at the specified value for a period of 60 seconds. There shall be 15 measurements per connector sample. During the withstanding voltage test, the fault and leakage indicators shall be monitored. A failure is the occurrence of a disruptive discharge by flashover (surface discharge), sparkover (air discharge), breakdown (puncture discharge) or leakage in excess of 5mA.

Pass/Fail: Pass

10.3 Insulation Resistance

Requirements:
Measurements shall be performed and recorded with reference to EIA-364-21D. A test voltage of 500 VDC shall be applied between most closely spaced contacts and between connector shell. The test samples shall be a plug and receptacle mated together. The test voltage shall be maintained at the specified value for a period of two minutes. The insulation resistance shall be a minimum of 5,000MΩ. There shall be 15 measurements per mated pair.

Pass/Fail: Pass

10.4 Low Level Contact Resistance

Requirements:
Measurements shall be performed and recorded with reference to EIA-364-23. Applied current shall be 100 mA. Testing shall be performed on all contact positions per mated connector pair. Measurements shall be taken from the press-fit compliant tail on the receptacle side to the press-fit compliant tail on the plug side. Resistance measurements shall not exceed 10 mΩ maximum.

Pass/Fail: Pass

10.5 Sterilization Type 3 Ethylene Oxide (100% EtO)

The sterilization method for Group 1 and 2 will consist of performing 2 cycles of the Ethylene Oxide sterilization process.

All samples will be sent to Nelson Labs, one of BWI's contract ETO sterilization facilities for (2) x ETO Sterilization cycles per SOP-QAD-004. Evidence of sterilization and number of sterilization cycles to be attached to the test report.

Acceptance Criteria: There is no acceptance criterion for this procedure; this is only for simulated conditioning.

Pass/Fail: Pass

10.6 Accelerated Aging

The units shall be subjected to artificial aging per ASTM F1980-07 for an accelerated 3-year aging at 95°C as calculated below.

- Accelerated Aging Factor (AAF)
  - $AAF=Q_{10}^{[(T_{AA}-T_{RT})/10]}$
  - T_{AA} = accelerated aging temperature (°C) = 95°C
  - T_{RT} = ambient temperature = 23°C
  - Q_{10} = 2
  - $AAF = 2.0^{7.2} = 147.0$
- Accelerated Aging Time (AAT)
  - AAT = Desired Shelf Life = RT/AAF
  - RT = number of days = 365 days/year * 3 years plus 1 month = 1130 days (Shelf Life)
  - AAT = 1130/147.0 = 7.8 days (7 days 21 hours)
- Place into a humidity chamber for 7.7 days
  - Temperature set to 95°C
  - Humidity will be ambient

Pass/Fail: Pass

10.7 Chemical Wipe-down

The cable samples will be subjected to up to 20 cycles of simulated disinfection and cleaning. Using CaviWipesTM which is a wipe towelette containing 17.2% IPA.
Procedure:
All samples will be subjected to a simulated cleaning wipe down to begin with using a lint-free cloth soaked in sterile water.
Using a wipe towelette (Isopropanol 17.2%, Diisobutylphenoxyethoxyethyldimethylbenzyl ammonium chloride 0.28%) wipe the entire surface of the cable from one end to the other end (holding the cable connector at one end) to simulate manual cleaning of the cable. Use another Wipe towelette to thoroughly wet the surface of the article and wipe to remove visible soil. Allow the articles to stand in ambient conditions until visibly dry. Avoid wiping the cable connector.

Pass/Fail: Pass

10.8 Sterilization Steam Autoclave

The sterilization method for Group 1 will consist of performing 20 cycles as detailed below:

Steam Autoclave

Flash	
Number of Cycles	20 total
Sterilizer Type	Gravity
Temperature	135˚C ±1ºC
Sterilization Cycle Time	10 minutes
Time between cycles	60 minutes

Note: At the end of the 10-minute sterilization stage, there is a cool-down period that must implement a drying stage. The autoclave may enable post-vacuum and heaters to dry the parts. This stage will have a duration of approximately 15 minutes. At the completion of an autoclave sterilization cycle and before making electrical measurements, parts must be fully dry.

Pass/Fail: Pass

10.9 Post-Sterilization Dielectric Withstanding Voltage

Refer to Section 10.2.

Pass/Fail: Pass

10.10 Post-Sterilization Insulation Resistance

Refer to Section 10.3.

Pass/Fail: Pass

10.11 Post-Sterilization Low Level Contact Resistance (LLCR)

Refer to Section 10.4.

Pass/Fail: Pass

10.12 Pre-Durability Connector Mating and Unmating Forces

Requirements:

With latch disengaged, connectors shall be tested in accordance with EIA-364-13, method A. Connectors shall be terminated, mounted to a fixture, and tested with a force gage. Connectors shall be gradually mated/unmated at a rate of 1.0 inch per minute. Mating force shall be ≤8.5 lbf. Unmating force shall be ≤7.0 lbf.

The two mating connectors shall be brought to a position where mechanical mating begins and the force, or torque gage, is at zero indication. The connectors shall mate until full engagement and the peak force required for mating shall be recorded. The mated connectors shall be fully un-mated, and the peak force required shall be recorded.

Pass/Fail: Pass

10.13 Durability (Connector Mating Cycles)

Requirements:

The connectors shall be tested in accordance with EIA-364-09. Align connector test samples. 25,000 mate and un-mate cycles shall be performed using a special holding fixture and connectors shall be automatically cycled at a rate of less than 500 mating cycles per hour. LLCR shall be performed, and all contacts shall be examined at .5k, 1k, 5k, 10k,cycles.

Pass/Fail: Pass

10.14 Low Level Contact Resistance (Durability)

Requirements:

Measurements shall be performed and recorded with reference to EIA-364-23. Applied current shall be 100 mA. Testing shall be performed on all contact positions per mated connector pair. Measurements shall be taken from the press-fit compliant tail on the

receptacle side to the press-fit compliant tail on the plug side. Resistance measurements shall not exceed 10 mΩ maximum.
Measurements shall be taken at .5k, 1k, 5k, and every 5k cycles up to 10k cycles.

Pass/Fail: Pass

10.15 Post Durability Connector Mating and Un-Mating Forces

Refer to Section 10.12.

Pass/Fail: Pass

10.16 Latch Retention Force

Requirements:
When tested with reference to AAMI-EC53, section 5.5.9, the connectors shall be pulled by the cable axially along the direction of connection. the minimum force required to separate the connection shall be met.
Latch Retention Force: 7 lbf minimum (at end of life)

Acceptance Criteria:

1. The connectors shall stay latched when subjected to the 7 lbf of axial force.
2. No damage to latch (broken).

Pass/Fail: Pass

10.17 Pre Bend-Flex Drop Cable Resistance

Requirements:
Measurements shall be performed and recorded to characterize the resistance of all conductors in the sample cables.

Pass/Fail: Pass

10.18 Pre Bend-Flex Drop Dielectric Withstanding Voltage

Refer to Section 10.2.

Pass/Fail: Pass

10.19 Pre Bend-Flex Drop Insulation Resistance

Refer to Section 10.3.

Pass/Fail: Pass

10.20 Bend Flex

Requirements:

Attach a weight to the free end of the cable using a clamp. Ensure that the total mass of the weight and clamp is 0.23 kg (± 5%) if the cable diameter (d) including the jacket is ≤ 3.2 millimeters (mm). If the cable diameter including the jacket is > 3.2 mm, use the following formula to calculate the total mass of the weight and clamp to use: Total mass = 0.0072 * π * d2 (± 5%). Rotate the flexing fixture through 100 flexes. One flex is defined as rotation from 0 to 90 degrees, back to –90 degrees, and back to 0 degrees. No fracture of jacket observed within 25 mm of the weight attachment position.

Pass/Fail: Pass

10.21 Post Bend-Flex Cable Resistance

Requirements:

Measurements shall be performed and recorded and shall be ≤ baseline measurement *1.5 to the resistance of all conductors in the sample cables.

Pass/Fail: Pass

10.22 Post Bend-Flex Dielectric Withstanding Voltage

Refer to Section 10.2.

Pass/Fail: Pass

10.23 Post Bend-Flex Insulation Resistance

Refer to Section 10.3.

Pass/Fail: Pass

10.24 Contact Insertion & Extraction forces

Requirements:

Per test procedure EIA-364-05C, ten (10) randomly chosen contacts to test on one (1) Plug Insulator.

The insertion tool shall be engaged in the approved manner. Sufficient force shall be applied to insert the contact into its normal mounting position in the connector. This force shall be recorded.

The removal tool shall be engaged with the contact and the contact locking device in the approved manner. Sufficient force shall be applied to release the locking mechanism and effect the removal of the contact. The maximum force shall be recorded.

1. Maximum contact insertion on plug insulator shall be ≤ 6.0 lbs.
2. Contact retention forces on plug insulator shall be ≥ 10.0 lbs.

Pass/Fail: Pass

10.25 Temperature Rise

Requirements:
The connectors shall be tested in accordance with EIA-364-70B, Method 1 to validate that the D04 connectors meet or exceed the defined connector temperature rise specifications.

Test current: 1.5 amperes (actual requirement)
Additional: Reference only test current: 2.0 amperes
Random contact locations to be tested throughout the insulators

Characterization testing to determine the amperage that yields a temperature rise of 30 degrees Celsius and a temperature rise of 70 degrees Celsius. Amperage shall be increased in steps of 0.2 ampere.

Pass/Fail: Pass

10.26 Crimp Tensile

Requirements:
Measurements shall be performed and recorded with reference to EIA-364-08C. The tensile strength of a crimped contact to conductor joint for each of the following wires/contact combinations shall meet the below:

#28 shall be greater than 1.0 lbf
#30 shall be greater than 0.8 lbf

Each stranded wire, gauge (#28, and #30 AWG) shall be tested individually, five (5) crimped samples of each size of wire.

Pass/Fail: Pass