

# Qualification Test Report

## HYPERGRIP SERIES – Qualification of MR contact in HG4 Receptacle Connector

June 2nd, 2021



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## 1. Scope

The purpose of this document is to define the test samples, test sequence, and test methods required to complete qualification of a Smiths HG4 Receptacle connector with the new MR socket contact technology.

## 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

All test samples utilized in the design validation will be fully assembled mated pair connectors where appropriate.

Table 1: Description of Test Articles

Part Number	Qty.	Description
<b>Group 1 (Contact-Level Performance - Mating)</b>		
203-1009639-975	30	MR Socket 0.4mm
YPN004-028G	30	Standard HG 0.4mm Pin
<b>Group 2 (Contact-Level Performance - Termination)</b>		
203-1009639-975	15	MR Socket 0.4mm
YSK004-041	5	Standard HG Socket, 0.4mm
<b>Group 3 (Contact-Level Performance – Installation/Retention)</b>		
203-1009639-975	99	MR Socket 0.4mm
ZHG033-001	3	HG4 Receptacle Insulator
<b>Group 4 (Connector level performance -Current Carrying Capacity)</b>		
854-1011427-900	3	HG4 Receptacle Assy with MR contact
854-1011426-900	3	HG4 Plug Assembly
<b>Group 5 (Connector-Level Performance – EtO Sterilization)</b>		
854-1011427-900	2	HG4 Receptacle Assy with MR contact
854-1011426-900	2	HG4 Plug Assembly
<b>Group 6 (Connector-Level Performance – Sterilization Groups-Autoclave, Sterrad and VHP)</b>		
854-1011427-900	6	HG4 Receptacle Assy with MR contact
854-1011426-900	6	HG4 Plug Assembly

## 4. Standard Ambient Test Conditions

All tests and examinations specified by this qualification 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: 86 kPa to 106 kPa

## 5. References

### Electronic Industries Alliance (EIA)

EIA-364-23	Low Level Contact Resistance Test Procedure for Electrical Connectors and Sockets
EIA-364-37C	Contact Engagement and Separation Test Procedure for Electrical Connectors
EIA-364-05B	Contact insertion, release and removal force test procedure for electrical connectors
EIA-364-08	Crimp Tensile Strength Test Procedure for Electrical Connectors
IPC/ECA J-STD-002C	Solderability tests for component leads, Terminations, Lugs, Terminals and wires
EIA-364-13D	Mating and Unmating Force 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-364-09	Durability Test Procedure for Electrical Connectors and Contacts
EIA-364-42	Impact test procedure for Electrical Connectors

### American Society for testing and materials (ASTM)

ASTM F1980	Standard guide for accelerated aging of sterile barrier systems for medical devices
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### Smiths Interconnect

ANSI/NCSL Z540-1-1994	Calibration System Requirements
QMM 400A	Smiths Connectors Quality Assurance Manual

## 6. Test Equipment and Facilities

### Test Equipment

Table 2 lists the equipment to be use during the performance of the testing required herein. Equivalent items may be used, if the effectiveness and accuracy of the tests are not adversely affected. Substitutes will be note in Table 2.

Manufacturer	Description	Model # / Serial #
GW INSTRON	Mill-Ohmmeter	GOM-802 / GCN921594
Mark-10	Force Gauge	M5-50/ 3492951
Mark-10	Motorized Test Stand	ESM301L / 3472924
Test Equity	Temperature / Humidity Chamber	1007H / 61185
Fluke	Temp Gauge	52 / 6420109
DAQAQ	Data Logger	DI-245 / 5C3E0237
Weneco Solder Pot with Controller Omega RDXL4SD	Solder Pot	RDXL4SD / 1.359780
Graphtec	Data Logger GT-5	GL240 / C00535458
Fluke	DMM	179 / 98180570
Fluke	Current Clamp	i310s / 29300057
Protek	Power Supply	3003B / AG0459
QuadTech	Hipot Tester	Sentry 20 / 7526750
Quad Tech	IR Tester	1866 / 7516745
Cincinnati Sub Zero	Temperature / Humidity Chamber	CT-32-10-10-s/wc / 99-CT13505
DNB Eng.	Impact Test Fixture	DTF364.42 / S4541

Table 2: Test Equipment

### Facilities

Smiths Interconnect may use its own facilities or any commercial laboratory that is approved internally, unless otherwise specified.

## 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 Connectors Quality Assurance will verify that all test data and collection methods are accurate and reliable.

## 8. Test Sequence

The test sequence shall go through qualification testing as per Table 3.

**Table 3: Test Sequence**

Test Procedure	Paragraph Reference	Pass/Fail Criteria
FAI -3 pcs dimensional and cross-section for plating coverage (termination and clip holes; clip ) and thickness, 9.1		
<b>DVT test for Breakdown voltage 2020-09-020 DVT TP</b>		
<b>Group 1 (30 new sockets with std. pins)</b>		<b>Pass/Fail Criteria</b>
Low Level Contact Resistance (LLCR)	9.3	Target $\leq 12.0 \text{ m}\Omega$
Contact Insertion force	9.4	Target $\leq 0.75\text{N}$ (2 <sup>nd</sup> cycle or later)
Contact Extraction force	9.4	Target $\leq 0.45\text{N}$
<b>Group 2 (15 new sockets, 5 std. sockets)</b>		<b>Pass/Fail Criteria</b>
Crimp Tensile test	9.5	Visual examination to check for flakes/cracks Minimum crimp retention $\geq 3\text{lbs}$ with 28AWG
Solderability test	9.6	Visual examination, Photos, cross-section
<b>Group 3 (99 new sockets, 3 insulators)</b>		<b>Pass/Fail Criteria</b>
Contact installation force	9.7	Target $\leq 20 \text{ lbs.}$
<b>Group 4 (3 samples)</b>		<b>Pass/Fail Criteria</b>
Wired Resistance	9.15	
Current carrying capacity	9.8	Target: 1A for each contact: $\leq 30^\circ\text{C}$ resulting temp. rise
<b>Group 5 (EtO Sterilization group, 2 Mated samples) Tests before and after sterilization</b>		<b>Pass/Fail Criteria</b>
Visual Inspection	9.2	Photos focusing on damage to socket, socket plating, or insulators – notable damage will need to be qualitatively examined to determine if any issues
Wired Resistance	9.15	
Mating/Unmating force	9.11	Target: Mating $\leq 6.4 \text{ lbs.}$ (with latch); Target: Unmating $\leq 7.2 \text{ lbs.}$ (with latch);
Dielectric withstanding voltage (DWV)	9.9	Target $\geq 1125 \text{ V}$
Insulation Resistance (IR)	9.10	Target: $> 5 \times 10^4 \text{ M}\Omega$ at 500 VDC
Accelerated Aging (3 Years)	9.13.1	N/A
Visual inspection	9.2	Photos focusing on damage to socket, socket plating, or insulators – notable damage will need to be qualitatively examined to determine if any issues
Wired Resistance	9.15	
Mating/Unmating force	9.11	Target: Mating $\leq 6.4 \text{ lbs.}$ (with latch); Pass/Fail: TBD

		Target: Unmating ≤ 7.2 lbs. (with latch); Pass/Fail: TBD
Insulation Resistance (IR)	9.10	Target: >5X10 <sup>4</sup> MΩ at 500 VDC
EtO sterilization: 2 Cycles	9.13.3	Visual inspection
Visual inspection	9.2	Photos focusing on damage to socket, socket plating, or insulators – notable damage will need to be qualitatively examined to determine if any issues
Wired Resistance	9.15	
Mating/Unmating force	9.11	Target: Mating ≤ 6.4 lbs. (with latch); Target: Unmating ≤ 7.2 lbs. (with latch);
Insulation Resistance (IR)	9.10	Target: >5X10 <sup>4</sup> MΩ at 500 VDC
Durability and Endurance up to 2000 cycles	9.12	Visual inspection at 100, 300, 500,750, 1k,1.5k and 2k – Photos required if notable conditions
Wired Resistance @ 100, 300, 500, 750, 1k, 1.5k and 2k cycles	9.15	
Mating/Unmating force @ 100, 300,500,750, 1k,1.5k 2k	9.11	Target: Mating ≤ 6.4 lbs. (with latch); Target: Unmating ≤ 7.2 lbs. (with latch)
Insulation Resistance (IR) @ 500,1k,1.5k,2k	9.10	Target: >5X10 <sup>4</sup> MΩ at 500 VDC
<b>Group 6 (Sterilization group, 6 Mated samples)</b>		<b>Pass/Fail Criteria</b>
<b>Tests before sterilization</b>		
Visual Inspection	9.2	Photos focusing on damage to socket, socket plating, or insulators – notable damage will need to be qualitatively examined to determine if any issues
Wired Resistance	9.15	
Mating/Unmating force	9.11	Target: Mating ≤ 6.4 lbs. (with latch); Target: Unmating ≤ 7.2 lbs. (with latch)
Dielectric withstanding voltage (DWV)	9.9	Target ≥ 1125 V
Insulation Resistance (IR)	9.9	Target: >5X10 <sup>4</sup> MΩ at 500 VDC
Durablity and Endurance up to 200 cycles	9.12	Visual inspection at 100 and 200 cycles – Photos required if notable conditions
Wired Resistance@ 100 & 200 cycles	9.15	
Mating/Unmating force @ 100 & 200 cycles	9.11	Target: Mating ≤ 6.4 lbs. (with latch); Target: Unmating ≤ 7.2 lbs. (with latch)
Insulation Resistance (IR)	9.9	Target: >5X10 <sup>4</sup> MΩ at 500 VDC
Accelerated Aging (3 Years)	9.13.1	N/A
Visual inspection	9.2	Photos focusing on damage to socket, socket plating, or insulators – notable damage will need to be qualitatively examined to determine if any issues
Wired Resistance	9.15	
Mating/Unmating force	9.11	Target: Mating ≤ 6.4 lbs. (with latch); Target: Unmating ≤ 7.2 lbs. (with latch)
Insulation Resistance (IR)	9.10	Target: >5X10 <sup>4</sup> MΩ at 500 VDC
<b>Group 6A (Autoclave, 2 Samples)</b>		<b>Pass/Fail Criteria</b>
Sterilization- Autoclave 20 cycles	9.13.2	Autoclave shall be performed to 3 min (Pre-Vac method) @ 135°C for 20 cycles
<b>Group 6B (Sterrad, 2 Samples)</b>		<b>Pass/Fail Criteria</b>

Sterilization- Sterrad 20 cycles	9.13.4	Visual inspection
<b>Group 6C (VHP, 2 Samples)</b>		<b>Pass/Fail Criteria</b>
Sterilization- VHP 20 cycles	9.13.5	Visual inspection
<b>Group 6 (Sterilization group, 6 mated samples) Post sterilization tests</b>		<b>Pass/Fail Criteria</b>
Visual Inspection	9.2	Photos focusing on damage to socket, socket plating, or insulators – notable damage will need to be qualitatively examined to determine if any issues
Wired Resistance	9.15	
Mating/Unmating force	9.11	Target: Mating ≤ 6.4 lbs. (with latch); Target: Unmating ≤ 7.2 lbs. (with latch)
Insulation Resistance (IR)	9.10	Target: >5X10 <sup>4</sup> MΩ at 500 VDC
Durability and Endurance up to 2000 cycles	9.12	Visual inspection @ 300, 500, 750, 1k, 1.5k and 2k cycles – Photos required if notable conditions
Wired Resistance @ 300, 500, 750, 1k, 1.5k and 2k cycles	9.15	
Mating/Unmating force @ 300,500,750, 1k,1.5k 2k	9.11	Target: Mating ≤ 6.4 lbs. (with latch); Target: Unmating ≤ 7.2 lbs. (with latch)
Insulation Resistance (IR) @ 500,1k,1.5k,2k	9.10	Target: >5X10 <sup>4</sup> MΩ at 500 VDC

## 9. Test Procedures

### 9.1 Visual and Mechanical

#### Requirements:

Full first article inspection report.

Note: Connector assemblies and detail parts or subassemblies shall be examined per Smiths Interconnect’s customer use drawing and shall meet the requirements specified herein.

### 9.2 Visual Examination

The mated connectors shall be examined according to IEC 60512-2, Test 1a. As is stated within this spec, examinations of the following features shall be made under magnification:

- a) workmanship and finish;
- b) marking;
- c) materials;
- d) surface finish, e.g.:
  - wearing/removal of material/plating
  - traces of corrosion,
  - colour (comparison with applicable colour standards or samples),
  - degree of lustre (comparison with applicable standard, e.g. Boll's scale or sample),



- foreign material in and on the surface;
- e) internal conditions of translucent materials (e.g. cavities, gaseous inclusions and flow lines, including inclusions of foreign matter);
- f) loosened and detached parts (especially after stress).

There shall be no deficiency criteria defined, but any deviations relative to previous checks shall be noted.

### 9.3 Low Level Contact Resistance (LLCR)

The connectors are to be tested in accordance with EIA-364-23. The test samples shall be connected as for normal service. The test shall use a constant current source of 100mA and 20 millivolts open circuit voltage. All contacts shall be measured. The target resistance shall be 10-12 mΩ.

Note: For measuring the LLCR for the discrete contacts in Group 1, place probes on each side where there is not any cross-sectional interference between the pin tip and the socket (see drawing of socket below, this should be around the midpoint of each contact). Keep probe placement consistent for all measurements. This shall be the only deviation from EIA-364-23.

#### Acceptance Criteria:

All contacts shall measure below 12 milliohms per contact.

Test Results		
Groups Tested	Number of specimens to be tested	Pass/Fail
Group 1	30 Loose Contacts	Pass

### 9.4 Contact Insertion/Extraction force

The contacts are to be tested in accordance with EIA-364-37C method A. The test samples shall be connected as for normal service. Axial forces shall be applied on contact gradually; rate of application not to exceed 0.051 meter per minute (2 inches per min). Depth of engagement shall be specified. The maximum size gauge shall be engaged to the specified depth and the force required to mate the gauge shall be measured. The minimum size gauge shall be engaged to the specified depth. The gauge shall then be withdrawn and force required to withdraw the gauge shall be measured. Contact forces must be tested in a manner that eliminates the effects of transverse forces, perpendicular to the direction of mating.

#### Acceptance Criteria:

Insertion Force: Average insertion force shall be lower than 0.75 newtons.

Extraction Force: Average extraction force shall be lower than 0.45 newtons.

Test Results		
Groups Tested	Number of specimens to be tested	Pass/Fail
Group 1 Insertion Force	30 Loose Contacts	Pass
Group 1 Extraction Force	30 Loose Contacts	Pass

### 9.5 Crimp Tensile Strength

10 pieces of the Sockets, 203-1009639-975 shall be crimped with 28 AWG wire to the contacts. The test shall be in accordance with the EIA-364-08 specification. The axial load required to pull the wire from the crimp barrel or break the wire shall not be less than the standard socket’s performance, estimated at 3 lbs min. Visual examination to check for flakes or cracks.

#### Acceptance Criteria:

Force required to separate crimped wire from crimp junction must be greater than 3 lbs. for all samples tested.

Test Results		
Groups Tested	Number of specimens to be tested	Pass/Fail
Group 2	10 Loose Contacts	Pass

### 9.6 Solderability test

5 Sockets are to be tested in accordance with IPC/ECA J-STD-002C. Solderability evaluations are made to verify that the solderability of component leads and terminations meet the requirements established in this standard and to determine that storage has had no adverse effect on the ability to solder components to an interconnecting substrate.

#### Acceptance Criteria:

At 10X magnification all samples shall exhibit a continuous solder coating free from defects for a minimum of 95% of the critical area of any individual lead. Dewetting, non-wetting and pin holes are cause for rejection.

Test Results		
Groups Tested	Number of specimens to be tested	Pass/Fail
Group 2	5 Loose Contacts	Pass

9.7 Installation force

Contacts installation force shall be tested as per EIA-364-05B. An axial load to the contact at a maximum rate of 25.4 millimeters per min until the contact retention features have been loaded into position. The maximum force required to load the contact shall be recorded. Contact forces must be tested in a manner that eliminates the effects of transverse forces, perpendicular to the direction of mating.

- a. Installation force: Start in center and work outwards, inspect for cracking

**Acceptance Criteria:**

Installation Force: Average installation force shall be lower than 20 lbs. per contact.

Test Results		
Groups Tested	Number of specimens to be tested	Pass/Fail
Group 3 Installation Force	99 Contacts, 3 Insulators	Pass

9.8 Current Carrying Capacity

When tested as specified in EIA-364-70B, the connectors shall not exceed the temperature as specified amperage determined during initial characterization testing. The target current shall be 1A +/- 10% for each energized contact. During the initial characterization testing the current shall be applied at 0.2 ampere to verify the 30 degrees Celsius rise level and then increased in steps of 0.2 ampere until a max ambient temp. of 125°C.

**Acceptance Criteria:**

Measured at ambient temperature:

Minimum 1A +/- 10% at a 30 °C temperature rise for 6 most inner contacts (28-33) energized.

Test Results		
Groups Tested	Number of specimens to be tested	Pass/Fail
Group 4	3 Connector Pairs	Pass

### 9.9 Dielectric Withstanding Voltage

Wired mated connectors shall be tested in accordance with EIA-364-20E, method B. The connector material can withstand the required voltage without breakdown and the contacts shall show no evidence of breakdown or flashover. The maximum leakage current shall be 2 milliamperes. DWV is targeted to be 1125 peak voltage. The DWV shall be tested across contact positions 1-17, 29-30, and 32-33.

#### Acceptance Criteria:

The connector contacts shall show no evidence of breakdown or flashover.

Test Results		
Groups Tested	Number of specimens to be tested	Pass/Fail
Group 5	2 Connector Pairs	Pass
Group 6	6 Connector Pairs	Pass

### 9.10 Insulation Resistance (IR)

Wired Receptacle connectors shall be tested in accordance with EIA-364-21E. The insulation resistance of the material between contacts shall be  $5 \times 10^4$  megohms at 500VDC. The insulation resistance measurements shall be made after a two-minute period of uninterrupted test voltage application.

#### Acceptance Criteria:

The insulation resistance must exceed 50,000 MΩ.

Test Results		
Groups Tested	Number of specimens to be tested	Pass/Fail

Group 5 – Post Ethylene Oxide Sterilization	2 Connector Pairs	Pass
Group 6 - Post Steam Autoclave Sterilization	2 Connector Pairs	Pass
Group 6 - Post VHP Sterilization	2 Connector Pairs	Pass
Group 6 - Post Sterrad Sterilization	2 Connector Pairs	Pass
Group 5 – Post 2000 Mating Cycles	2 Connector Pairs	Pass
Group 6 - Post 2000 Mating Cycles	6 Connector Pairs	Pass

### 9.11 Mating/Un-mating force

The Wired connectors are to be tested in accordance with EIA-364-13, Method A. The two mating connectors shall be brought to a position where mechanical mating begins and the force or torques gage is at zero indication. The connectors mate until full engagement and the peak force or torque required for mating shall be recorded. The mated connectors shall be fully unmated at a rate of 25.4 millimeters/minute and the peak force or torque required shall be recorded. Connectors must be tested in a manner that eliminates the effects of transverse forces, perpendicular to the direction of mating.

#### Acceptance Criteria:

Average Maximum Mating Force for Test Group = 6.4 lbs.

Average Minimum Mating Force for Test Group = 7.2 lbs.

Test Results		
Groups Tested	Number of specimens to be tested	Pass/Fail
Group 5 – Post Ethylene Oxide Sterilization	2 Connector Pairs	Pass
Group 6 - Post Steam Autoclave Sterilization	2 Connector Pairs	Pass
Group 6 - Post VHP Sterilization	2 Connector Pairs	Pass
Group 6 - Post Sterrad Sterilization	2 Connector Pairs	Pass
Group 5 – Post 2000 Mating Cycles	2 Connector Pairs	Pass

Group 6 - Post 2000 Mating Cycles	6 Connector Pairs	Pass
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### 9.12 Durability and Endurance test

The Wired connectors are to be tested in accordance with EIA-364-09. The connectors will be mated and unmated for 2,000 cycles. The Automatic, circular connector mating/unmating cycle rate per hour shall be 250 to 300 (or maximum in referenced testing standard) maximum. The connectors or contact shall be examined to determine the effects of durability cycling that would include following.

- a. Observe and photograph any buildup of residue or removal of material
- b. Measure LLCR
- c. Measure mating and unmating force
- d. Measure IR

**There are no Pass/Fail criteria for this test.**

### 9.13 Sample conditioning

#### 9.13.1 Accelerated Aging

**Purpose:** To simulate three years of use by aging each sample in an accelerated manner using an elevated temperature. The units shall be subjected to artificial aging per ASTM F1980. Accelerated aging regimen will be based on Arrhenius reaction rate function (i.e. chemical reactions contributing to material degradation double in rate for each additional 10°C aging temperature above real-time service temperature) for an expected service temperature of 22°C (72°F). Humidity will be ambient.

**Test Samples: Group 5, Group 6**

**Calculations:**

<b>Accelerated Aging Factor (AAF)</b>	
$AAF = Q_{10}^{[(T_{aa}-T_{rt})/10]}$	111.43
Taa = Accelerated aging temperature	90°C
Trt = ambient temperature	22°C
Q <sub>10</sub>	2
<b>Accelerated Aging Time (AAT)</b>	
AAT = Desired Shelf Life (RT)/AAF	1095/111.43 or 9.8 Days
RT = Number of Days	1095

**There are no Pass/Fail criteria for this test.**

### 9.13.2 Steam Autoclave

**Purpose:** To expose the connectors to the sterilization process likely to be encountered when employed in reusable equipment and applications for which sterilization is performed in a hospital setting.

**Test Samples: Group 6A (2 Samples)**

**Test Parameters:**

<i>Steam Autoclave</i>	
Number of Cycles	20
Sterilizer Type	Vacuum
Temperature	135°C +3/-0 Per AAMI ST8
Temperature Exposure time	3 mins
Full Cycle Time	2hrs
Time between cycles	30min

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.

**There are no Pass/Fail criteria for this test.**

### 9.13.3 Ethylene Oxide (EtO/EO) Sterilization

**Purpose:** To expose the connector to the sterilization process likely to be encountered during packaging or for multi-use applications.

**Test Samples: Group 5**

**Test Parameters:**

<i>Ethylene Oxide Gas</i>	
Number of Cycles	2
<b>Pre-Conditioning</b>	
Temperature	43°C (110°F)
Relative Humidity	55%
Duration	8 hrs. min
<b>EtO Exposure</b>	
Temperature	54°C (130°F)
Initial Vacuum	1.30 PSIA
Steam Addition	0.49 PSIA rise (23% RH)

Steam Dwell Time	30 minutes
EtO Gas Concentration	590 mg/L of 100% EtO
EtO Gas Dwell Time	2 hours
Air Washes	3x
<b>Aeration</b>	
Temperature	43°C (110°F)
Duration	1 hrs min

**There are no Pass/Fail criteria for this test.**

### 9.13.4 Sterrad Sterilization

**Purpose:** To expose the connector to the sterilization process likely to be encountered during packaging or for multi-use applications.

**Test Samples: Group 6B (2 Samples)**

**Test Parameters:**

<b><i>Sterrad</i></b>	
Number of Cycles	20
Cycle Type	Standard
Temperature	22°C to 27°C
Cycle Duration	47 min
Dwell Time Between Cycled (Cool Down)	30 min ± 5 min

**There are no Pass/Fail criteria for this test.**

### 9.13.5 VHP Sterilization

**Purpose:** To expose the connector to the sterilization process likely to be encountered during packaging or for multi-use applications.

**Test Samples: Group 6C (2 Samples)**

**STERIS® V-PRO\* MAX 2 Non Lumen STERILIZATION Cycle Parameters:**

Each NON LUMEN CYCLE sterilization pulse is determined following a condition phase ("C"). During the Sterilization Phase ("S"), the pressure rises in the chamber to approximately 500 Torr followed by a deep vacuum, which brings the pressure to 1 Torr during exposure. This is considered one (1) NON LUMENCYCLE sterilization pulse. A total of four (4) sterilization pulses are contained within each full NONLUMEN CYCLE.



**There are no Pass/Fail criteria for this test.**

9.14 Wired Resistance

**Test Samples: Group 5, Group 6**

The connectors are to be tested in accordance with EIA-364-23. The test shall use a constant current source of 100mA and 20 millivolts open circuit voltage. All contacts shall be measured. The resistance shall be measured between the pins of the attached D-sub, and the connectors shall be mated during the measurement.

**Acceptance Criteria:**

Average resistance per contact must remain below 12 milliohms after Ethylene Oxide sterilization and 2000 mating cycles.

Contacts must retain proper functioning after steam autoclave sterilization and 2000 mating cycles.

Test Results		
Groups Tested	Number of specimens to be tested	Pass/Fail
Group 5 – Post Ethylene Oxide Sterilization and 2000 mating cycles	2 Connector Pairs	Pass
Group 6 - Post Steam Autoclave Sterilization and 2000 mating cycles	2 Connector Pairs	Pass
Group 6 - Post VHP Sterilization and 2000 mating cycles	2 Connector Pairs	Pass
Group 6 - Post Sterrad Sterilization and 2000 mating cycles	2 Connector Pairs	Pass