

Qualification Test Report

Eclipta Connector Testing

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Jason Kutnink, 01/23/2018



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1 Definition of Terms

Acronym	Definition
°C	degrees Celsius
∅	diameter
±	plus-minus sign, indicating a tolerance or margin of error
A	ampere
AAF	accelerated aging factor
AAT	accelerated aging time
Amp	ampere
CCC	current carrying capacity
DWV	dielectric withstanding voltage
EtO	ethylene oxide
ft	foot or feet
IR	insulation resistance
LC	long contact
lbf	pound-force
LLCR	low level contact resistance
m	meter
mΩ	milliohm
MΩ	megaohm
max	maximum
mm	millimeter
N	number (of samples); Newton (unit of force)
Q ₁₀	aging factor for 10°C increase or decrease in temperature
RT	real time conditions
SC	short contact
T _{AA}	accelerated aging temperature
T _{RT}	ambient temperature
V	volts
VDC	volts of direct current

Table 1: List of Acronyms and Definitions

2 Scope

The purpose of this document is to define the test samples, test sequence, test methods, and test results in order to validate the Eclipta Product Line.

3 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.

4 Description of Test Specimen

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

PN	Description
ECL34PRA	Reusable Plug Connector , A Key
ECL34EDA	Disposable Receptacle Connector, A Key

Table 2: Description of Test Specimens

5 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: 21°C to 27°C
Relative Humidity: 20% to 80%
Barometric Pressure: 725 +50 –70 mm Hg

6 References

Electronic Industries Alliance (EIA)

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 364-20	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 Leadwires
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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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International Electrotechnical Commission (IEC)

ANSI/IEC 60529	Degrees of Protection Provided by Enclosures (IP Code)
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Smiths Interconnect

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

7 Test Equipment and Facilities

7.1 Test Equipment

Table 3 lists the equipment to be used 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 noted in Table 3.

Manufacturer	Description and Model	Smiths Interconnect Serial Number
Keithley	2700 Multimeter/Data Acquisition System	35-902
Keithley	2700 Multimeter/Data Acquisition System	35-903
Mark-10 Corporation	BG50 Digital Force Gauge	10-455
HYPOTULTRA	7800 Dielectric Analyzer	35-901
	R3D3	35-0865
	HCT	35-0867
Sun Electronic Systems, Inc.	EC11 Environmental Chamber	35-917
	Pneumatic Cyclor	01470
Priorclave	Autoclave, PNA/QVA/EH150M	20461

Table 3: Test Equipment

7.2 Facilities

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

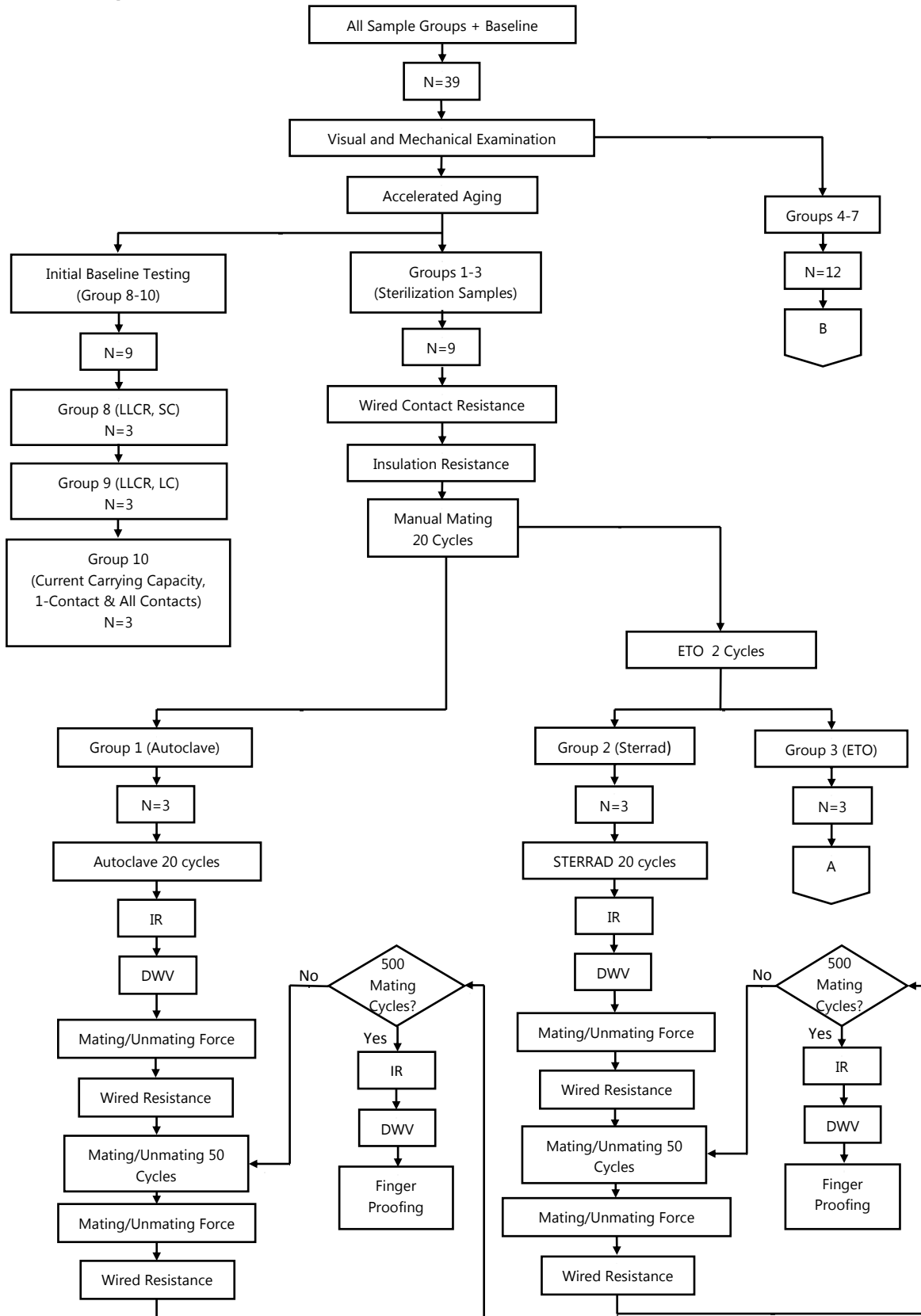
8 Calibration

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.

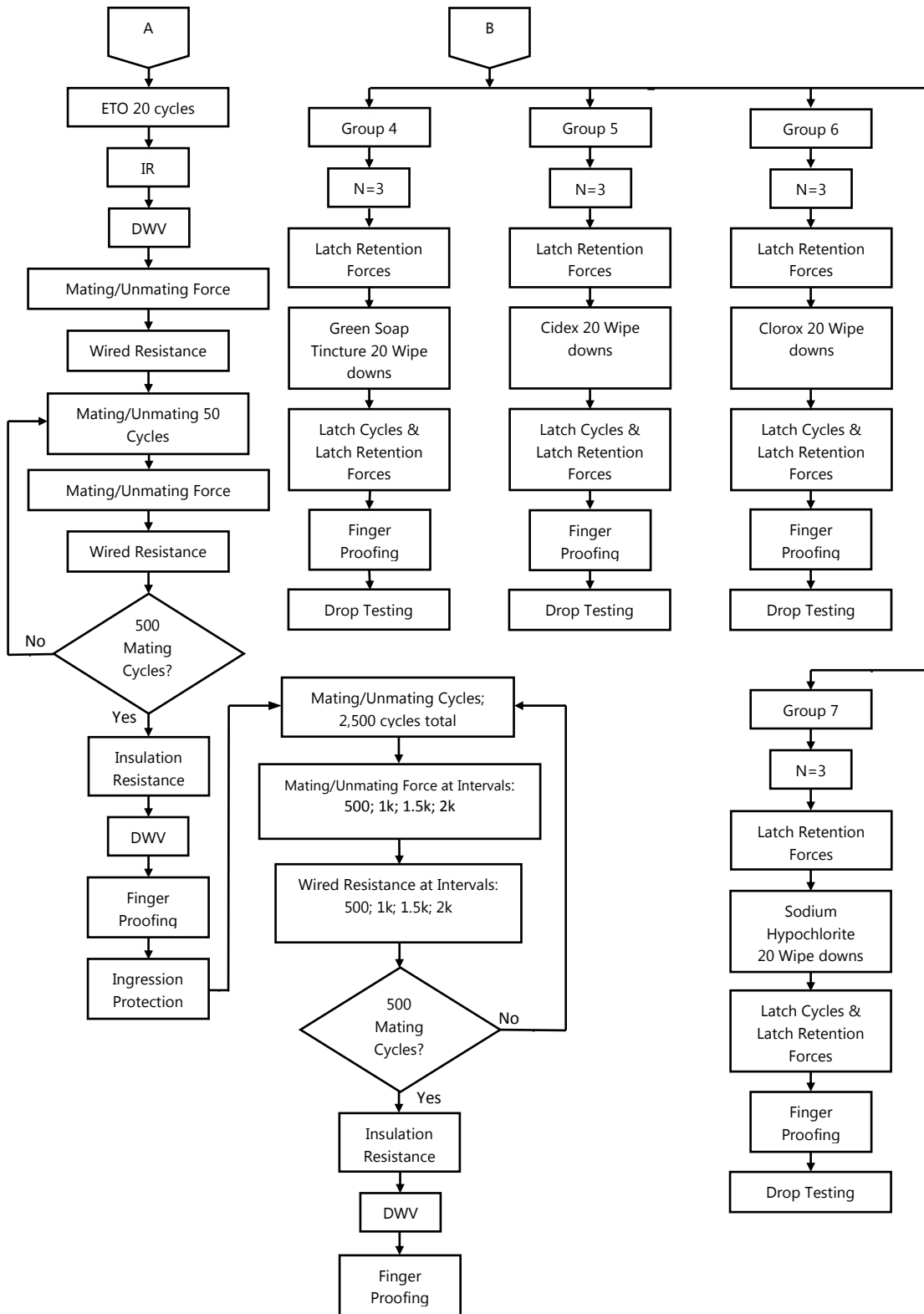
9 Test Sequence

The test procedures shall be broken into ten groups. Three groups will be used to establish baseline product performance: Low-Level Contact Resistance - Short Contacts (LLCR, SC); Low-Level Contact Resistance - Long Contacts (LLCR, LC); and Current Carrying Capacity (CCC). The remaining seven groups will be used for sterilization and disinfectant testing. The testing groups each consist of 3 mated pairs of connectors. Each group of connectors will go through the listed tests in the order specified in the Test Flow Sequence below:

Test Flow Sequence



Test Flow Sequence (continued)



10 Test Procedures and Results

10.1 Visual and Mechanical

Connector assemblies and detail parts or subassemblies shall be examined as specified in part drawings and shall meet the requirements specified.

10.2 Accelerated Aging Conditioning

The units shall be subjected to artificial aging per ASTM F1980 for an accelerated 3 year aging at 80°C as calculated below.

- Accelerated Aging Factor(AAF)
 - $AAF = Q_{10}^{[(T_{AA} - T_{RT})/10]}$
 - T_{AA} = accelerated aging temperature (°C) = 80°C
 - T_{RT} = ambient temperature = 22°C
 - $Q_{10} = 2$
 - $AAF = 2.0^{5.8} = 55.7$

- Accelerated Aging Time(AAT)
 - $AAT = \text{Desired Shelf Life} = RT/AAF$
 - $RT = \text{number of days} = 365 \text{ days/year} * 3 \text{ years} = 1095 \text{ days (Shelf Life)}$
 - $AAT = 1095/55.7 = 19.66 \text{ days (19 days 16 hours)}$

- Place into a humidity chamber for 19.66 days
 - Temperature set to 80°C
 - Humidity will be ambient

Test Setup		
Accelerated Aging Time (AAT)	19.66	Days
Accelerated Aging Temperature (T_{AA})	80	Degrees Celsius
Humidity	Ambient	
Number of specimens to be tested	18	Mated Cable Sets

10.3 Baseline Testing

10.3.1 Current Carrying Capacity (CCC)

Scope:

The units were tested to prove that the connectors are capable of meeting the specified Current Carrying Capacity requirements. The connectors were modified to enable temperature measurement as close to the center of the energized circuit connection(s) as is reasonably possible. This testing was conducted on samples that underwent accelerated aging conditioning only.

Test Specification:

EIA-364-70B

Test Procedure:

Single Contact Energized:

Starting Current: 0.2A

Stepping Current: 0.2A

Dwell Time: 5 min

Maximum Allowable Temperature Rise: 30°C

All Contacts Energized:

Starting Current: 5A (Combined current in all contacts)

Stepping Current: 5A (Combined current in all contacts)

Dwell Time: 5 min

Maximum Allowable Temperature Rise: 30°C

Acceptance Criteria:

Measured at ambient temperature:

Minimum 2.5A +/- 10% at a 30°C temperature rise for a single energized contact

Minimum 0.5A +/- 10% at a 30°C temperature rise for all contacts energized

Test Results		
Groups Tested	Number of specimens to be tested	Pass/Fail
Group 10 – CCC Single Contact	3 Mated Pairs (Reusable Plug/ Disposable Receptacle)	Pass
Group 10 – CCC All Contacts	3 Mated Pairs (Reusable Plug/ Disposable Receptacle)	Pass

10.4 Sterilization Conditioning Groups

10.4.1 Sterilization Type 1 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 ±1°C
Full Cycle Time	10 minutes
Time between cycles	30 minutes

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. All testing must take place no less than three hours after Autoclave Sterilization.

Note: Only reusable plugs were sterilized.

10.4.2 Sterilization Type 2 Sterrad®

The sterilization method for Group 2 will consist of performing 20 cycles of the Sterrad sterilization process as detailed below:

Test Requirements: Sterrad® 100NX

Number of Cycles	20
Cycle Type	Standard
Temperature in °C	Ambient
Cycle Duration	47 minutes
Dwell time between cycles (cool down)	30 minutes ± 5 minutes

Note: Only reusable plugs were sterilized.

10.4.3 Sterilization Type 3 Ethylene Oxide (100% EtO)

The sterilization method for Group 3 will consist of performing 20 cycles of the Ethylene Oxide sterilization process.

Note: Disposable receptacles were only sterilized for 2 cycles.

10.4.4 Connector Mating Cycles

Scope:

The units were mated up to the designated mating cycle life requirements to prove that the contact connections have adequate durability. Mating cycles were only conducted after environmental conditioning to test worst-case performance.

Test Specification:

EIA-364-09C

Test Procedure:

Connectors are mated together with an automated system to the mating cycle life requirements below:

500 Mating Cycles: Groups 1 and 2 (Autoclave and Sterrad® Sterilization Groups)

2,500 Mating Cycles: Group 3 (EtO Sterilization Group)

Acceptance Criteria:

The contacts/connectors shall not be damaged at the end of cycle life.

At the end of cycle life, the connectors shall meet the following requirements (details of each parameter below are contained in the Acceptance Criteria for each specific test):

Electrical Parameters:

- a. Low-Level Contact Resistance
- b. Dielectric Withstanding Voltage
- c. Insulation Resistance

Mechanical Parameters:

- a. Mating/unmating force
- b. Finger proofing
- c. Ingression protection

Note: The connector latch was removed to facilitate cycling on Groups 1, 2 and 3.

Test Results		
Groups Tested	Number of specimens to be tested	Pass/Fail
Group 1 – Steam Autoclave Sterilization	3 Mated Pairs (Reusable Plug/ Disposable Receptacle)	Pass
Group 2 – Sterrad® Sterilization	3 Mated Pairs (Reusable Plug/ Disposable Receptacle)	Pass
Group 3 – Ethylene Oxide Sterilization	3 Mated Pairs (Reusable Plug/ Disposable Receptacle)	Pass

10.4.5 Low-Level Contact Resistance (LLCR)

Scope:

The units were tested to prove that the connectors are capable of meeting the specified Low-Level Contact Resistance requirements. The connectors were modified to enable measurement across the contact interface. Utilizing wired connections, resistance testing was conducted before and after environmental conditioning and mating cycles, the latter of which was to test worst-case performance.

Test Specification:

EIA-364-23C (Exceptions: Test Current and Open-Circuit Voltage; wired resistance measurements taken during mating cycles used two-wire measurement technique).

Test Procedure:

Units are measured across the contact interface using the following test current: 1mA and open circuit voltage: 6.6V.

Acceptance Criteria:

Measured at ambient temperature:

Average Low-Level Contact Resistance of contact interface to be $\leq 0.040 \Omega$ per contact after accelerated aging, environmental conditioning, and mating cycles.

Test Results		
Groups Tested	Number of specimens to be tested	Pass/Fail
Group 1 – Steam Autoclave Sterilization	3 Mated Pairs (Reusable Plug/ Disposable Receptacle)	Pass
Group 2 – Sterrad® Sterilization	3 Mated Pairs (Reusable Plug/ Disposable Receptacle)	Pass
Group 3 – Ethylene Oxide Sterilization	3 Mated Pairs (Reusable Plug/ Disposable Receptacle)	Pass
Group 3 – High Cycle Life	3 Mated Pairs (Reusable Plug/ Disposable Receptacle)	Pass

10.4.6 Dielectric Withstanding Voltage (DWV)

Scope:

The units were tested to prove that the connectors are capable of meeting the specified dielectric withstanding voltage requirements. This testing was conducted before and after environmental conditioning and mating cycles, the latter of which was to test worst-case performance.

Test Specification:

EIA-364-20E, Method B

Test Procedure:

The voltage shall be applied between 5 contacts and the closest adjacent contacts. The test voltage shall be raised uniformly from zero to 550 V then held for 60 seconds at maximum withstanding voltage.

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 1 – Steam Autoclave Sterilization	3 Mated Pairs (Reusable Plug/ Disposable Receptacle)	Pass
Group 2 – Sterrad® Sterilization	3 Mated Pairs (Reusable Plug/ Disposable Receptacle)	Pass
Group 3 – Ethylene Oxide Sterilization	3 Mated Pairs (Reusable Plug/ Disposable Receptacle)	Pass

10.4.7 Insulation Resistance (IR)

Scope:

The units were tested to prove that the connectors are capable of meeting the specified insulation resistance requirements. This testing was conducted before and after environmental conditioning and mating cycles, the latter of which was to test worst-case performance.

Test Specification:

EIA-364-21E

Test Procedure:

The voltage shall be applied between 5 contacts and the closest adjacent contacts. The test voltage shall be raised uniformly from zero to 500 V then held for 60 seconds at this test voltage.

Acceptance Criteria:

The insulation resistance must exceed the following values:

Group 1 (Autoclave Sterilization):

Before Sterilization/Cycling: $\geq 5,000 \text{ M}\Omega$

After Sterilization/Cycling: $\geq 1,000 \text{ M}\Omega^*$

Group 2 (Sterrad® Sterilization) and Group 3 (EtO Sterilization/High-Cycle Life) :

Before and After Sterilization/Cycling: $\geq 5,000 \text{ M}\Omega$

Test Results		
Groups Tested	Number of specimens to be tested	Pass/Fail
Group 1 – Steam Autoclave Sterilization	3 Mated Pairs (Reusable Plug/ Disposable Receptacle)	Pass
Group 2 – Sterrad® Sterilization	3 Mated Pairs (Reusable Plug/ Disposable Receptacle)	Pass
Group 3 – Ethylene Oxide Sterilization	3 Mated Pairs (Reusable Plug/ Disposable Receptacle)	Pass
Group 3 – High Cycle Life	3 Mated Pairs (Reusable Plug/ Disposable Receptacle)	Pass

***ADDITIONAL NOTES:** Worst-case performance if not dried; if properly dried after Autoclave, performance returns to $\geq 5,000 \text{ M}\Omega$.

10.4.8 Connector Mating and Un-Mating Forces

Scope:

The units were tested by measuring the force required to fully mate and unmate the connectors to prove adequate force requirements. This testing was conducted after environmental conditioning and mating cycles to test worst-case performance.

Test Specification:

EIA-364-13D, Method A

Test Procedure:

The connectors are pushed and pulled axially along the direction of the connection to determine if the forces required to connect and separate the connection are within the specified parameters.

Acceptance Criteria:

Maximum Mating Force = 8.5 lbf

Maximum Unmating Force = 7.0 lbf

Note: The connector latch was removed to facilitate cycling on Groups 1, 2 and 3.

Test Results		
Groups Tested	Number of specimens to be tested	Pass/Fail
Group 1 – Steam Autoclave Sterilization	3 Mated Pairs (Reusable Plug/ Disposable Receptacle)	Pass
Group 2 – Sterrad® Sterilization	3 Mated Pairs (Reusable Plug/ Disposable Receptacle)	Pass
Group 3 – Ethylene Oxide Sterilization	3 Mated Pairs (Reusable Plug/ Disposable Receptacle)	Pass

10.4.9 Finger Proofing

Scope:

The units were tested for finger proofing. Finger proofing tests were conducted after environmental conditioning and mating cycles to test worst-case performance. Group 3 samples (EtO Sterilization) were then cycled up to 2,500 total mating cycles and tested again.

Test Specification:

ANSI/IEC 60529-2004

Test Procedure:

A jointed test finger with a stop face measuring Ø 50 mm x 20 mm is used to verify adequate clearance to hazardous parts. A low-voltage supply between 40V to 50V in series with a suitable lamp shall be connected between the probe and the hazardous parts inside the enclosure. The jointed test finger is pushed against the openings of the enclosure with a force of 10N ± 10%.

Acceptance Criteria:

The jointed test finger shall not touch hazardous live parts; the lamp shall not light.

Note: Finger proofing testing was only performed on the reusable plug side of each mated pair of cables.

Test Results		
Groups Tested	Number of specimens to be tested	Pass/Fail
Group 1 – Steam Autoclave Sterilization	3 Reusable Plugs	Pass
Group 2 – Sterrad® Sterilization	3 Reusable Plugs	Pass
Group 3 – Ethylene Oxide Sterilization	3 Reusable Plugs	Pass
Group 3 – High Cycle Life	3 Reusable Plugs	Pass

10.4.10 Ingression Testing

Scope:

The units were ingress tested to a rating of IP30. Testing was for solid foreign objects of Ø 2.5mm and greater; this testing does not prove protection for liquids. This testing was conducted after environmental conditioning and mating cycles to prove worst-case performance.

Test Specification:

ANSI/IEC 60529-2004

Test Procedure:

The access probe is pushed against any openings of the enclosure with a force of 3N ± 10%.

Acceptance Criteria:

A test rod of Ø 2.5 mm shall not penetrate and adequate clearance shall be kept.

Note: Ingression testing was only performed on the reusable plug side of each mated pair of cables.

Test Results		
Group Tested	Number of specimens to be tested	Pass/Fail
Group 3 – High Cycle Life	3 Reusable Plugs	Pass

10.5 Disinfectant Conditioning Groups

10.5.1 Green Soap Tincture Wipe

The units shall be wiped down with a cloth dampened with green soap tincture solution. Each unit shall be exposed to 20 cycles of full external wipe down. The wiping process shall not be fully wetting but shall lightly coat the connector with the cleaning solution. The green soap tincture is "Green Works" manufactured by The Clorox Company.

Note: *Wipedown was applied to both reusable plug and disposable receptacle.*

10.5.2 Cidex

The units shall be wiped down with a cloth dampened with cidex solution. Each unit shall be exposed to 20 cycles of full external wipe down. The wiping process shall not be fully wetting but shall lightly coat the connector with the cleaning solution. The cidex is "MetriCide sterilizing & disinfecting solution" manufactured by Metrex Research.

Note: *Wipedown was applied to both reusable plug and disposable receptacle.*

10.5.3 Clorox

The units shall be wiped down with a Clorox wipe. Each unit shall be exposed to 20 cycles of full external wipe down. The wiping process shall not be fully wetting but shall lightly coat the connector with the cleaning solution. The Clorox wipes are "Clorox Disinfecting Wipes" manufactured by The Clorox Company.

Note: *Wipedown was applied to both reusable plug and disposable receptacle.*

10.5.4 Sodium Hypochlorite 10% concentration (Bleach)

The units shall be wiped down with a cloth dampened with sodium hypochlorite solution. Each unit shall be exposed to 20 cycles of full external wipe down. The wiping process shall not be fully wetting but shall lightly coat the connector with the cleaning solution. The sodium hypochlorite is manufactured by Fisher.

Note: *Wipedown was applied to both reusable plug and disposable receptacle.*

10.5.5 Latch Cycles

Scope:

The units were mated up to 2,500 cycles to prove the connector latching mechanism has adequate durability. Mating cycles were only conducted after environmental conditioning to test worst-case performance.

Test Specification:

EIA-364-09

Test Procedure:

Connectors are mated together with an automated system up to 2,500 mating cycles.

Acceptance Criteria:

The connectors shall not be damaged at the end of cycle life.

Latch Retention Force requirement shall be maintained throughout cycle life.

Test Results		
Groups Tested	Number of specimens to be tested	Pass/Fail
Group 4 – Green Soap Tincture Disinfection	3 Mated Pairs (Reusable Plug/ Disposable Receptacle)	Pass
Group 5 – Cidex Disinfection	3 Mated Pairs (Reusable Plug/ Disposable Receptacle)	Pass
Group 6 – Bleach Disinfection	3 Mated Pairs (Reusable Plug/ Disposable Receptacle)	Pass
Group 7 – Clorox Disinfection	3 Mated Pairs (Reusable Plug/ Disposable Receptacle)	Pass

10.5.6 Latch Retention Force

Scope:

The connectors were pulled by the cable to prove latch effectiveness. This testing was conducted after environmental conditioning and mating cycles to prove out worst-case performance.

Test Specification:

AAMI-EC53, section 5.3.6

Test Procedure:

The connectors are pulled by the cable axially along the direction of connection to the minimum force requirement.

Acceptance Criteria:

1. The connectors shall stay latched when subjected to the 7 lbf of axial force.
2. No damage to latch shall occur that compromises latch retention performance.

Test Results		
Groups Tested	Number of specimens to be tested	Pass/Fail
Group 4 – Green Soap Tincture Disinfection	3 Mated Pairs (Reusable Plug/ Disposable Receptacle)	Pass
Group 5 – Cidex Disinfection	3 Mated Pairs (Reusable Plug/ Disposable Receptacle)	Pass
Group 6 – Bleach Disinfection	3 Mated Pairs (Reusable Plug/ Disposable Receptacle)	Pass
Group 7 – Clorox Disinfection	3 Mated Pairs (Reusable Plug/ Disposable Receptacle)	Pass

10.5.7 Drop Impact

Scope:

The units were tested to prove adequate drop impact resistance. This testing was conducted after environmental conditioning and mating cycles to test worst-case performance.

Test Specification:

EIA-364-42

Test Procedure:

Each of the assemblies shall be dropped from a minimum of 1.2 m (4 ft.) drop, 8 times at different orientations.

Acceptance Criteria:

Each of the assemblies shall withstand the drop impacts without any noticeable fracture or failure that could affect connector functionality as follows:

- Latch Retention Force requirement of 7lbf minimum shall be achieved after drops.

Note: Drop Impact testing shall only be performed on the reusable plug side of each mated pair of cables.

Test Results		
Groups Tested	Number of specimens to be tested	Pass/Fail
Group 4 – Green Soap Tincture Disinfection	3 Reusable Plugs	Pass
Group 5 – Cidex Disinfection	3 Reusable Plugs	Pass
Group 6 – Bleach Disinfection	3 Reusable Plugs	Pass
Group 7 – Clorox Disinfection	3 Reusable Plugs	Pass