

White paper

Autoclavable D series



Background:

Autoclaving is often used to sterilize medical devices to prevent disease transmission both in new and reusable products. Autoclaves sterilize by introducing high pressure steam into a chamber containing the objects to be sterilized. Therefore, these devices must be able to withstand autoclaving temperatures in the range of 135°C without damage, deformation, or disintegration.

Autoclave sterilization of mechanical surgical and dental instruments used in invasive procedures is well known and has been used for many decades to assure the equipment is free of dangerous contamination (viruses, bacteria, fungus, etc.). Traditionally, these instruments are made of metals (such as stainless steel or anodized aluminum) which can easily withstand the autoclave environment. Similarly, electronic medical equipment often must also be sterilized between patients, but since these typically contain plastic components, care must be taken to choose plastics which will endure many of these steam sterilization cycles.

The electronic connectors used on these electronic medical devices need to bear the autoclave environment as well. However connectors can be made with a variety of plastics, so to be autoclavable, the plastic from which these are crafted must not melt, deflect, or change their electrical properties during the process.

D series connectors:

Smiths Interconnect's D series plastic circular connectors, with their simple and intuitive push-button latching, and high reliability Hypertac® contacts, are ideal for many medical applications, including electrophysiology catheters, patient monitors, MRI systems, intravascular ultrasounds, defibrillators, infusion pumps, and laboratory equipment. Versions of the D series are available in either polycarbonate (Lexan™)* or polyetherimide (Ultem™)*. The higher temperature Ultem plastic exceeds the temperature range of typical autoclave systems, therefore allowing for autoclave sterilization of the connectors.

*Lexan and Ultem are trademarks of Sabic Innovative Plastics

Autoclave testing of Ultem D Series connectors:

To assure that these connectors with Ultem housings could be used in applications requiring autoclave sterilization, Smiths Interconnect ran a range of tests on the following connectors (note: the "U" in the part numbers signifies Ultem plastic components):

- 4 position D01
 - D01PB406MSUT
 - Male cable plugs with gold plated screw machined pins
 - Mating female panel receptacles with gold plated Hypertac sockets
 - ZDU104 receptacle insulator with YSK006 sockets (std. receptacle p/n would be: D01EEB406FSUTAH)
- 12 position D02
 - D02PB125MSUT
 - Male cable plugs with gold plated screw machined pins



- Mating female panel receptacles with gold plated Hypertac sockets
 - ZDU212 receptacle insulator with YSK005 sockets (std. receptacle p/n would be: D02EEB125FSUTAH)

The D series plugs (unmated), with their contacts terminated to individual wires, were exposed to 20 autoclave cycles, pre-vacuum method, each for 4 minutes at 135°C. Low level contact resistance, on mated pairs of connectors, as well as mating and unmating force measurements were taken before and after autoclave cycling and compared to assure there were no significant differences, and that they continue to meet predetermined requirements. Then the connectors were mated and unmated 200 times to assure that no substantial changes occurred. Finally, the dielectric withstanding voltage was checked on each connector pair confirming that the insulators continued to meet the design specification.



Test outcomes were as follows: (ref: QTP 2018-12-043 RPT, rev A.1, dtd: 1-31-2019):

Low Level Contact Resistance Test:

- Date: 1/30/2019
- Job number: DD-194639
- Specification: EIA-364-23C
- Test environment:
 - Temperature: 23.1°C
 - Relative Humidity: 32.5%
 - Barometric Pressure: 995.6 hPa
- Test equipment: Keithley 5A Source Meter 2440 (calibration due: 8/30/2019)
- Requirements: Contact resistance (mated contacts soldered to 3" to 6" lengths of 24AWG wires) must be less than or equal to the following:
 - D01: 10 mΩ per contact (5 mΩ max contact resistance spec plus termination wires)
 - D02: 16 mΩ per contact (8 mΩ max contact resistance spec plus termination wires)
- Measurements (mΩ):

Baseline LLCR D01			
Mated Pair			
Pin	1	2	3
1	7.7	8.3	7.8
2	8.1	8.4	7.7
3	7.9	8.0	7.6
4	8.3	7.9	7.7

Post Autoclave LLCR D01			
Mated Pair			
Pin	1	2	3
1	8.4	9.2	8.1
2	8.4	9.1	7.7
3	8.7	8.5	8.2
4	8.0	7.9	8.7

Baseline LLCR D02			
Mated Pair			
Pin	1	2	3
1	13.7	13.7	14.3
2	14.3	13.3	14.9
3	13.5	13.7	14.9
4	14.6	14.1	14.2
5	13.7	13.3	15.2
6	13.7	14.0	14.5
7	13.9	13.2	15.0
8	14.1	13.2	14.1
9	14.5	13.1	14.3
10	13.6	13.4	14.4
11	13.8	14.4	15.2
12	14.1	13.7	14.3

Post Autoclave LLCR D02			
Mated Pair			
Pin	1	2	3
1	13.6	13.5	14.5
2	14.5	13.2	14.6
3	13.5	13.6	14.5
4	13.9	14.0	14.3
5	13.5	13.5	15.6
6	13.6	13.9	14.9
7	13.5	13.1	15.1
8	14.2	13.5	14.5
9	14.1	13.4	14.4
10	13.7	13.1	14.8
11	13.5	14.1	15.4
12	14.2	13.8	14.2

- End result: **PASS**

Mating/Unmating Force (Durability) Test:

- Date: 1/30/2019
- Job number: DD-194639
- Specification: EIA-364-09C / EIA-364-13D
- Test environment:
 - Temperature: 23.1°C
 - Relative Humidity: 32.5%
 - Barometric Pressure: 995.6 hPa
- Test equipment: Mark-10 Force Gauge BG2 (calibration due 2/28/2019)
- Requirements:
 - Durability tested per EIA-364-09C
 - Connector pairs mated and unmated for 200 cycles at a rate of 300 cycles per hour min
 - Note: Push button latch depressed and disengaged during unmate force test
 - Mating and unmating forces tested per EIA-364-13D
 - Visual inspection taken after cycling to look for excessive wear as a failure
 - Post autoclave force measurements compared to pre-autoclave forces
- Measurements (lbs):
 - Note: D02 sample #2 latch mechanism damaged in set up

Baseline Mate/Unmate Force D01												
Mated Pair	Cycle 1 (lbs)		Cycle 2 (lbs)		Cycle 3 (lbs)		Cycle 4 (lbs)		Cycle 5 (lbs)		Average	
	Mate	Unmate	Mate	Unmate	Mate	Unmate	Mate	Unmate	Mate	Unmate	Mate	Unmate
1	1.49	0.79	1.50	0.96	1.52	0.79	1.48	0.84	1.43	0.82	1.48	0.84
2	1.21	1.01	1.20	1.03	1.20	1.04	1.19	1.02	1.17	1.01	1.19	1.02
3	1.76	0.81	1.72	0.90	1.70	0.90	1.68	0.94	1.68	0.92	1.71	0.89

Post AutoClave Mate/Unmate Force D01												
Mated Pair	Cycle 1 (lbs)		Cycle 2 (lbs)		Cycle 3 (lbs)		Cycle 4 (lbs)		Cycle 5 (lbs)		Average	
	Mate	Unmate	Mate	Unmate	Mate	Unmate	Mate	Unmate	Mate	Unmate	Mate	Unmate
1	1.31	0.65	1.22	0.76	1.14	0.81	1.16	0.67	1.22	0.64	1.21	0.70
2	1.31	0.98	1.30	0.88	1.28	1.16	1.22	1.18	1.28	1.01	1.28	1.04
3	1.43	0.64	1.34	0.72	1.38	0.86	1.40	1.01	1.41	0.95	1.39	0.84

Post Cycling Mate/Unmate Force D01												
Mated Pair	Cycle 1 (lbs)		Cycle 2 (lbs)		Cycle 3 (lbs)		Cycle 4 (lbs)		Cycle 5 (lbs)		Average	
	Mate	Unmate	Mate	Unmate	Mate	Unmate	Mate	Unmate	Mate	Unmate	Mate	Unmate
1	1.30	0.66	1.21	0.76	1.13	0.79	1.14	0.75	1.12	0.68	1.18	0.73
2	1.29	0.96	1.28	0.87	1.22	0.93	1.19	0.90	1.15	0.98	1.23	0.93
3	1.42	0.65	1.32	0.73	1.31	0.75	1.25	0.74	1.30	0.79	1.32	0.73

Mated Pair	Baseline Mate/Unmate Force D02											
	Cycle 1 (lbs)		Cycle 2 (lbs)		Cycle 3 (lbs)		Cycle 4 (lbs)		Cycle 5 (lbs)		Average	
	Mate	Unmate	Mate	Unmate	Mate	Unmate	Mate	Unmate	Mate	Unmate	Mate	Unmate
1	2.06	1.61	1.94	1.56	2.05	1.53	2.00	1.49	1.93	1.24	2.00	1.49
2												
3	1.82	1.06	1.85	1.15	1.71	1.20	1.79	1.12	1.79	1.02	1.79	1.11

Mated Pair	Post AutoClave Mate/Unmate Force D02											
	Cycle 1 (lbs)		Cycle 2 (lbs)		Cycle 3 (lbs)		Cycle 4 (lbs)		Cycle 5 (lbs)		Average	
	Mate	Unmate	Mate	Unmate	Mate	Unmate	Mate	Unmate	Mate	Unmate	Mate	Unmate
1	2.00	1.52	1.89	1.49	1.88	1.44	1.83	1.40	1.86	1.09	1.89	1.39
2												
3	1.90	1.15	1.84	1.10	1.80	1.12	1.82	1.09	1.79	1.01	1.83	1.09

Mated Pair	Post Cycling Mate/Unmate Force D02											
	Cycle 1 (lbs)		Cycle 2 (lbs)		Cycle 3 (lbs)		Cycle 4 (lbs)		Cycle 5 (lbs)		Average	
	Mate	Unmate	Mate	Unmate	Mate	Unmate	Mate	Unmate	Mate	Unmate	Mate	Unmate
1	1.91	1.49	1.84	1.47	1.78	1.44	1.78	1.42	1.79	1.22	1.82	1.41
2												
3	1.92	0.98	1.86	0.95	1.79	0.99	1.79	0.96	1.75	0.94	1.82	0.96

- End result: **PASS**

Dielectric Withstanding Voltage (DWV) Test:

- Date: 1/30/2019
- Job number: DD-194639
- Specification: EIA-364-20E
- Test environment:
 - Temperature: 23.1°C
 - Relative Humidity: 25.5%
 - Barometric Pressure: 995.6 hPa
- Requirements:
 - Withstanding voltage tested per EIA-364-20E, method C
 - D01 test:
 - Test voltage raised uniformly from zero to 1650V, then held for 60 seconds at maximum withstanding voltage
 - D02 test:
 - Test voltage raised uniformly from zero to 750V, then held for 60 seconds at maximum withstanding voltage
 - A failure occurs if an arc is detected
- Findings:

Dielectric Withstanding Voltage D01			
Pins	Mated Pair		
	1	2	3
1 to 2	PASS	PASS	PASS
1 to 3	PASS	PASS	PASS
1 to 4	PASS	PASS	PASS
4 to Shell	PASS	PASS	PASS

Dielectric Withstanding Voltage D02			
Pins	Mated Pair		
	1	2	3
5 to 3	PASS	PASS	PASS
5 to 4	PASS	PASS	PASS
5 to 10	PASS	PASS	PASS
6 to 1	PASS	PASS	PASS
6 to 7	PASS	PASS	PASS
6 to 8	PASS	PASS	PASS
9 to 11	PASS	PASS	PASS
9 to 12	PASS	PASS	PASS
7 to Shell	PASS	PASS	PASS
4 to Shell	PASS	PASS	PASS

- End result: **PASS**

Conclusion:

These D01 and D02 connectors made of high temperature Ultem polyetherimide plastic exhibit little or no change in performance after exposure to multiple autoclave sterilization cycles that are typically used in medical applications. Therefore, they are suitable for use in medical device designs which require this type of sterilization between uses.