

PACETM Evaluation

Technical Report

2 June 2014
Addendum: 14 August 2014

PREPARED EXPRESSLY FOR: B & D Product
2280 W 80 Street
Unit 7
Hialeah, FL 33016
USA
William Barrett
(305) 822-9422

PACE 4E026

REQUESTED BY: Paula Cannella
STERIS Corporation
Life Sciences Sales Representative

LABORATORY PROCESSING DIRECTED BY:

Charles A Johnston Technical Services Associate	Paul Lopolito Technical Services Specialist or Manager
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PROJECT DESCRIPTION

Determine the compatibility of:
PACE 4E026 – PharmcoTech FM Approved Standard 4882 (LN: 7022-83) with:

- Vesphene[®] IIst Sterile One-Step Germicidal Detergent (6861)
- Process LpHst[®] Sterile One-Step Cleaner Disinfectant (6841)
- Septihol[®] Sterile Alcohol Solution (6248)
- Spor-Klenz[®] Ready To Use Cold Sterilant (6525)
- 6% Hydrogen Peroxide Solution

STERIS[®]



STERIS Corporation
SCIENTIFIC Division

PO Box 147
St. Louis, MO 63166-0147 USA
1-800-345-0802

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PACETM Evaluation

Technical Report

PACE 4E026
Page 2

PROCEDURE

1. The sample coupons were supplied by B & D Product.
2. The sample coupons were weighed on an analytical balance to determine their tare weights.
3. The Thickness of the sample coupons was measured once at each edge using a Vernier caliper.
4. The Hardness of the sample coupons was measured in four different spots using a Shore D Hardness meter.
5. Sample coupons were dosed with ½ mL of use-dilutions of the cleaners.
 - i. Let stand for 10 minutes.
 - ii. Repeated for a total of 15 applications.
 - iii. Wiped with polyester wipe soaked with DI Water.
 - iv. Air-dried at ambient temperature for at least 15 minutes.
 - v. Weight, Thickness, and Hardness, were measured.
 - vi. Repeat steps i. to v. for another 15 applications.

Note: By the end of the testing, each sample coupon had received a total of 30 applications of the use-dilutions of the cleaners.



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PACETM Evaluation

Technical Report

PACE 4E026
Page 3

CONCLUSIONS AND RECOMMENDATIONS

PACE 4E026 – PharmcoTech FM Approved Standard 4882

The Vesphene IIst Detergent, Process LpHst Disinfectant, Septihol Alcohol Solution, Spor-Klenz Sterilant, and 6% Hydrogen Peroxide Solution, had similar compatibility against PACE 4E026 – PharmcoTech FM Approved Standard 4882 versus Deionized Water. The sample materials were compatible.

This data is intended to provide assistance in terms of evaluating the tested solutions for compatibility with the sample material. It is recommended that the end user perform independent evaluations and monitoring to ensure satisfactory chemical compatibility.

See Data Charts for details.



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PACETM Evaluation

Technical Report

PACE 4E026
Page 4

Addendum
14 August 2014

PROJECT DESCRIPTION

Determine the compatibility of:

PACE 4E026 – PharmcoTech FM Approved Standard 4882 with:

- 5.25% Sodium Hypochlorite
- 0.525% Sodium Hypochlorite

Test procedure is described in the PROCEDURE section above.

CONCLUSIONS AND RECOMMENDATIONS

PACE 4E026 – PharmcoTech FM Approved Standard 4882

The 0.525% Sodium Hypochlorite Solution and the 5.25% Sodium Hypochlorite Solution had similar compatibility against PACE 4E026 – PharmcoTech FM Approved Standard 4882 versus Deionized Water. The sample materials were compatible.

This data is intended to provide assistance in terms of evaluating the tested solutions for compatibility with the sample material. It is recommended that the end user perform independent evaluations and monitoring to ensure satisfactory chemical compatibility.

See Data Charts for details.



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PACETM Evaluation

Technical Report

PACE 4E026
Page 5

Included are the "Data Charts" listing the tests conducted in our laboratory. After reviewing this report, if you have any questions or if we can be of further assistance, please feel free to contact us.

All STERIS products must be handled in accordance with labeling and SDS instructions.

Sincerely,



Charles A Johnston
Technical Services Associate



Paul Lopolito
Technical Services Manager



STERIS Corporation
SCIENTIFIC Division
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B & D Product
PharmcoTech FM Approved Standard 4882
PACE 4E026

Detergent	Vesphene Ilist Detergent (6861)	Vesphene Ilist Detergent (6861)	Vesphene Ilist Detergent (6861)
Conc	1 oz/gal	1 oz/gal	1 oz/gal
Temperature	Ambient	Ambient	Ambient
Wt0 (g)	28.3079	29.0930	28.4832
Wt15 (g)	28.3106	29.9098	28.4803
Wt30 (g)	28.3090	29.0921	28.4813
Thickness 0 (mm)	2.08	2.10	2.12
	2.08	2.10	2.14
	2.08	2.10	2.13
	2.08	2.09	2.14
Average	2.08	2.10	2.13
Std Dev	0.000	0.005	0.010
Thickness 15 (mm)	2.08	2.09	2.12
	2.07	2.10	2.12
	2.08	2.09	2.11
	2.09	2.10	2.13
Average	2.08	2.10	2.12
Std Dev	0.008	0.006	0.008
Thickness 30 (mm)	2.08	2.08	2.12
	2.07	2.08	2.13
	2.07	2.08	2.11
	2.08	2.09	2.13
Average	2.08	2.08	2.12
Std Dev	0.006	0.005	0.010

Detergent	Vesphene Ilist Detergent (6861)	Vesphene Ilist Detergent (6861)	Vesphene Ilist Detergent (6861)
Temperature	1 oz/gal	1 oz/gal	1 oz/gal
Temperature	Ambient	Ambient	Ambient
Visual Appearance 0	White	White	White
Visual Appearance 15	White	White	White
Visual Appearance 30	White	White	White
Hardness 0 Shore A	77	76	75
	76	76	76
	77	76	76
	77	76	76
Average	77	76	76
Std Dev	0.5	0.0	0.5
Hardness 15 Shore A	76	76	76
	77	76	76
	75	76	76
	76	76	76
Average	76	76	76
Std Dev	0.8	0.0	0.0
Hardness 30 Shore A	75	76	75
	75	75	75
	75	75	76
	76	75	76
Average	75	75	76
Std Dev	0.5	0.5	0.6

B & D Product
PharmcoTech FM Approved Standard 4882
PACE 4E026

Detergent	LpHst Disinfectant (6841)	LpHst Disinfectant (6841)	LpHst Disinfectant (6841)
Conc	1/2 oz/gal	1/2 oz/gal	1/2 oz/gal
Temperature	Ambient	Ambient	Ambient
Wt0 (g)	28.9213	28.5797	27.6407
Wt15 (g)	28.9180	28.5783	27.6408
Wt30 (g)	28.9176	28.5789	27.6400
Thickness 0 (mm)	2.13	2.10	2.10
	2.12	2.10	2.10
	2.13	2.12	2.10
	2.13	2.11	2.10
Average	2.13	2.11	2.10
Std Dev	0.005	0.010	0.000
Thickness 15 (mm)	2.10	2.11	2.09
	2.11	2.09	2.09
	2.12	2.12	2.10
	2.12	2.11	2.09
Average	2.11	2.11	2.09
Std Dev	0.010	0.013	0.005
Thickness 30 (mm)	2.10	2.10	2.07
	2.10	2.08	2.08
	2.11	2.11	2.08
	2.11	2.09	2.08
Average	2.11	2.10	2.08
Std Dev	0.006	0.013	0.005

Detergent	LpHst Disinfectant (6841)	LpHst Disinfectant (6841)	LpHst Disinfectant (6841)
Temperature	1/2 oz/gal	1/2 oz/gal	1/2 oz/gal
Temperature	Ambient	Ambient	Ambient
Visual Appearance 0	White	White	White
Visual Appearance 15	White	White	White
Visual Appearance 30	White	White	White
Hardness 0 Shore A	76	75	75
	75	75	76
	75	75	75
	75	75	75
Average	75	75	75
Std Dev	0.5	0.0	0.5
Hardness 15 Shore A	77	76	77
	76	76	76
	77	76	75
	77	76	75
Average	77	76	76
Std Dev	0.5	0.0	1.0
Hardness 30 Shore A	76	76	76
	76	76	76
	75	76	76
	76	76	76
Average	76	76	76
Std Dev	0.5	0.0	0.0

B & D Product
PharmcoTech FM Approved Standard 4882
PACE 4E026

Detergent	Septihol Solution (6248)	Septihol Solution (6248)	Septihol Solution (6248)
Temperature	Ambient	Ambient	Ambient
Wt0 (g)	28.2936	28.5720	27.5604
Wt15 (g)	28.2988	28.5837	27.5606
Wt30 (g)	28.2963	28.5771	27.5606
Thickness 0 (mm)	2.08	2.08	2.07
	2.09	2.08	2.09
	2.09	2.08	2.07
	2.09	2.08	2.10
Average	2.09	2.08	2.08
Std Dev	0.005	0.000	0.015
Thickness 15 (mm)	2.09	2.10	2.07
	2.08	2.08	2.10
	2.08	2.10	2.08
	2.08	2.06	2.09
Average	2.08	2.09	2.09
Std Dev	0.005	0.019	0.013
Thickness 30 (mm)	2.09	2.10	2.08
	2.08	2.08	2.10
	2.06	2.09	2.07
	2.06	2.07	2.06
Average	2.07	2.09	2.08
Std Dev	0.015	0.013	0.017

Detergent	Septihol Solution (6248)	Septihol Solution (6248)	Septihol Solution (6248)
Temperature	Ambient	Ambient	Ambient
Visual Appearance 0	White	White	White
Visual Appearance 15	White	White	White
Visual Appearance 30	White	White	White
Hardness 0 Shore A	76	76	75
	76	76	76
	75	76	75
	76	75	75
Average	76	76	75
Std Dev	0.5	0.5	0.5
Hardness 15 Shore A	75	76	75
	77	76	75
	75	75	74
	76	76	75
Average	76	76	75
Std Dev	1.0	0.5	0.5
Hardness 30 Shore A	76	77	76
	76	76	75
	75	75	75
	75	75	75
Average	76	76	75
Std Dev	0.6	1.0	0.5

B & D Product
PharmcoTech FM Approved Standard 4882
PACE 4E026

Detergent	Spor-Klenz Disinfectant (6525)	Spor-Klenz Disinfectant (6525)	Spor-Klenz Disinfectant (6525)
Temperature	Ambient	Ambient	Ambient
Wt0 (g)	28.2339	28.7206	29.3783
Wt15 (g)	28.2334	28.7204	29.3764
Wt30 (g)	28.2379	28.7212	29.3774
Thickness 0 (mm)	2.11	2.06	2.09
	2.12	2.07	2.11
	2.13	2.60	2.10
	2.12	2.09	2.11
Average	2.12	2.21	2.10
Std Dev	0.008	0.264	0.010
Thickness 15 (mm)	2.12	2.07	2.08
	2.12	2.08	2.08
	2.14	2.06	2.12
	2.12	2.08	2.11
Average	2.13	2.07	2.10
Std Dev	0.010	0.010	0.021
Thickness 30 (mm)	2.11	2.07	2.08
	2.12	2.08	2.09
	2.13	2.06	2.11
	2.10	2.08	2.11
Average	2.12	2.07	2.10
Std Dev	0.013	0.010	0.015

Detergent	Spor-Klenz Disinfectant (6525)	Spor-Klenz Disinfectant (6525)	Spor-Klenz Disinfectant (6525)
Temperature	Ambient	Ambient	Ambient
Visual Appearance 0	White	White	White
Visual Appearance 15	White	White	White
Visual Appearance 30	White	White	White
Hardness 0 Shore A	76	76	76
	76	76	75
	76	75	75
	75	76	75
Average	76	76	75
Std Dev	0.5	0.5	0.5
Hardness 15 Shore A	75	75	76
	75	76	75
	75	75	75
	75	75	75
Average	75	75	75
Std Dev	0.0	0.5	0.5
Hardness 30 Shore A	76	76	76
	76	75	76
	75	75	75
	76	76	76
Average	76	76	76
Std Dev	0.5	0.6	0.5

B & D Product
PharmcoTech FM Approved Standard 4882
PACE 4E026

Detergent	6% Hydrogen Peroxide	6% Hydrogen Peroxide	6% Hydrogen Peroxide
Temperature	Ambient	Ambient	Ambient
Wt0 (g)	27.0205	27.8276	27.2448
Wt15 (g)	27.0242	27.8295	27.2467
Wt30 (g)	27.0230	27.8268	27.2429
Thickness 0 (mm)	2.08	2.12	2.14
	2.10	2.11	2.14
	2.10	2.12	2.13
	2.10	2.10	2.15
Average	2.10	2.11	2.14
Std Dev	0.010	0.010	0.008
Thickness 15 (mm)	2.10	2.10	2.14
	2.10	2.11	2.15
	2.10	2.12	2.14
	2.09	2.13	2.13
Average	2.10	2.12	2.14
Std Dev	0.005	0.013	0.008
Thickness 30 (mm)	2.09	2.10	2.15
	2.09	2.12	2.14
	2.08	2.10	2.14
	2.08	2.11	2.15
Average	2.09	2.11	2.15
Std Dev	0.006	0.010	0.006

Detergent	6% Hydrogen Peroxide	6% Hydrogen Peroxide	6% Hydrogen Peroxide
Temperature	Ambient	Ambient	Ambient
Visual Appearance 0	White	White	White
Visual Appearance 15	White	White	White
Visual Appearance 30	White	White	White
Hardness 0 Shore A	76	76	75
	75	76	76
	76	76	75
	76	76	76
Average	76	76	76
Std Dev	0.5	0.0	0.6
Hardness 15 Shore A	75	76	76
	75	75	76
	75	75	75
	76	75	75
Average	75	75	76
Std Dev	0.5	0.5	0.6
Hardness 30 Shore A	76	76	77
	75	76	76
	75	75	75
	75	75	76
Average	75	76	76
Std Dev	0.5	0.6	0.8

B & D Product
PharmcoTech FM Approved Standard 4882
PACE 4E026

Detergent	DI Water	DI Water	DI Water
Temperature	Ambient	Ambient	Ambient
Wt0 (g)	27.5974	30.0500	27.1486
Wt15 (g)	27.5961	30.0507	27.1471
Wt30 (g)	27.5954	30.0493	27.1467
Thickness 0 (mm)	2.1100	2.0800	2.1100
	2.1000	2.0900	2.1100
	2.1000	2.1000	2.1000
	2.1200	2.0800	2.0900
Average	2.1075	2.0875	2.1025
Std Dev	0.010	0.010	0.010
Thickness 15 (mm)	2.0900	2.1000	2.1000
	2.1100	2.0700	22.1100
	2.0900	2.0800	2.1000
	2.1000	2.0900	2.1100
Average	2.0975	2.0850	7.1050
Std Dev	0.010	0.013	10.003
Thickness 30 (mm)	2.1100	2.1100	2.1000
	2.1100	2.0700	2.1100
	2.1000	2.0700	2.1100
	2.1100	2.0900	2.1000
Average	2.1075	2.0850	2.1050
Std Dev	0.005	0.019	0.006

Detergent	DI Water	DI Water	DI Water
Temperature	Ambient	Ambient	Ambient
Visual Appearance 0	White	White	White
Visual Appearance 15	White	White	White
Visual Appearance 30	White	White	White
Hardness 0 Shore A	76	76	76
	76	76	76
	76	75	75
	76	75	76
Average	76	76	76
Std Dev	0.0	0.6	0.5
Hardness 15 Shore A	76	75	75
	76	76	76
	75	75	75
	76	75	75
Average	76	75	75
Std Dev	0.5	0.5	0.5
Hardness 30 Shore A	75	76	76
	75	75	77
	75	75	75
	76	75	76
Average	75	75	76
Std Dev	0.5	0.5	0.8

B & D Product
PharmcoTech FM Approved Standard 4882
PACE 4E026 Addendum

Date: 8/14/2014

Detergent	5.25% Sodium Hypochlorite	5.25% Sodium Hypochlorite	5.25% Sodium Hypochlorite
Temperature	Ambient	Ambient	Ambient
Wt0 (g)	27.2433	27.8146	27.9248
Wt15 (g)	27.2421	27.8116	27.9220
Wt30 (g)	27.2399	27.8091	27.9207
Thickness 0 (mm)	2.04	2.04	2.05
	2.04	2.05	2.05
	2.04	2.04	2.08
	2.04	2.04	2.08
Average	2.04	2.04	2.07
Std Dev	0.000	0.005	0.017
Thickness 15 (mm)	2.04	2.08	2.07
	2.05	2.04	2.09
	2.05	2.04	2.09
	2.04	2.05	2.07
Average	2.05	2.05	2.08
Std Dev	0.006	0.019	0.012
Thickness 30 (mm)	2.04	2.03	2.05
	2.03	2.03	2.08
	2.03	2.05	2.07
	2.04	2.03	2.04
Average	2.04	2.04	2.06
Std Dev	0.006	0.010	0.018

Detergent	5.25% Sodium Hypochlorite	5.25% Sodium Hypochlorite	5.25% Sodium Hypochlorite
Temperature	Ambient	Ambient	Ambient
Visual Appearance 0	White	White	White
Visual Appearance 15	White	White	White
Visual Appearance 30	White	White	White
Hardness 0 Shore A	76	77	77
	76	77	76
	77	76	76
	77	75	76
Average	77	76	76
Std Dev	0.6	1.0	0.5
Hardness 15 Shore A	75	76	76
	76	75	76
	75	76	76
	75	75	77
Average	75	76	76
Std Dev	0.5	0.6	0.5
Hardness 30 Shore A	76	75	76
	75	75	77
	75	76	77
	75	75	75
Average	75	75	76
Std Dev	0.5	0.5	1.0

B & D Product
PharmcoTech FM Approved Standard 4882
PACE 4E026 Addendum

Date: 8/14/2014

Detergent	0.525% Sodium Hypochlorite	0.525% Sodium Hypochlorite	0.525% Sodium Hypochlorite
Temperature	Ambient	Ambient	Ambient
Wt0 (g)	27.3392	27.1371	27.0394
Wt15 (g)	27.3410	27.1337	27.0403
Wt30 (g)	27.3366	27.1300	27.0365
Thickness 0 (mm)	2.02	2.08	2.10
	2.00	2.08	2.05
	2.02	2.08	2.07
	2.08	2.08	2.06
Average	2.03	2.08	2.07
Std Dev	0.035	0.000	0.022
Thickness 15 (mm)	1.95	2.07	2.06
	2.00	2.04	2.06
	2.07	2.06	2.10
	2.00	2.08	2.04
Average	2.01	2.07	2.07
Std Dev	0.049	0.010	0.025
Thickness 30 (mm)	2.00	2.04	2.06
	2.07	2.07	2.10
	2.03	2.08	2.04
	1.96	2.07	2.07
Average	2.02	2.07	2.07
Std Dev	0.047	0.017	0.025

Detergent	0.525% Sodium Hypochlorite	0.525% Sodium Hypochlorite	0.525% Sodium Hypochlorite
Temperature	Ambient	Ambient	Ambient
Visual Appearance 0	White	White	White
Visual Appearance 15	White	White	White
Visual Appearance 30	White	White	White
Hardness 0 Shore A	77	76	75
	76	75	77
	76	76	75
	75	75	77
Average	76	76	76
Std Dev	0.8	0.6	1.2
Hardness 15 Shore A	74	76	76
	76	76	75
	74	75	75
	76	75	77
Average	75	76	76
Std Dev	1.2	0.6	1.0
Hardness 30 Shore A	76	75	76
	75	75	75
	76	76	75
	75	74	76
Average	76	75	76
Std Dev	0.6	0.8	0.6

B & D Product
PharmcoTech FM Approved Standard 4882
PACE 4E026 Addendum

Date: 8/14/2014

Detergent	DI Water	DI Water	DI Water
Temperature	Ambient	Ambient	Ambient
Wt0 (g)	27.2230	29.0307	29.5391
Wt15 (g)	27.2221	29.0285	29.6174
Wt30 (g)	27.2204	29.0263	29.6163
Thickness 0 (mm)	2.10	2.06	2.08
	2.08	2.10	2.10
	2.08	2.08	2.08
	2.09	2.07	2.08
Average	2.09	2.08	2.09
Std Dev	0.010	0.017	0.010
Thickness 15 (mm)	2.08	2.08	2.08
	2.10	2.07	2.08
	2.07	2.10	3.10
	2.08	2.08	2.08
Average	2.08	2.08	2.34
Std Dev	0.013	0.013	0.510
Thickness 30 (mm)	2.08	2.05	2.07
	2.08	2.09	2.07
	2.06	2.07	2.08
	2.07	2.07	2.10
Average	2.07	2.07	2.08
Std Dev	0.010	0.016	0.014

Detergent	DI Water	DI Water	DI Water
Temperature	Ambient	Ambient	Ambient
Visual Appearance 0	White	White	White
Visual Appearance 15	White	White	White
Visual Appearance 30	White	White	White
Hardness 0 Shore A	77	76	77
	77	75	77
	77	75	77
	77	76	76
Average	77	76	77
Std Dev	0.0	0.6	0.5
Hardness 15 Shore A	77	76	76
	77	76	76
	77	76	76
	77	76	76
Average	77	76	76
Std Dev	0.0	0.0	0.0
Hardness 30 Shore A	76	76	76
	76	75	76
	76	76	76
	76	75	75
Average	76	76	76
Std Dev	0.0	0.6	0.5

B & D Product
PharmcoTech FM Approved Standard 4882
PACE 4E026 Addendum

Date: 8/14/2014

Detergent	Dry Blank	Dry Blank	Dry Blank
Temperature	Ambient	Ambient	Ambient
Wt0 (g)	27.3954	27.2667	27.2975
Wt15 (g)	27.3939	27.2658	27.2966
Wt30 (g)	27.3917	27.2634	27.2949
Thickness 0 (mm)	2.04	2.05	2.05
	2.04	2.04	2.06
	2.04	2.06	2.06
	2.04	2.06	2.06
Average	2.04	2.05	2.06
Std Dev	0.000	0.010	0.005
Thickness 15 (mm)	2.04	2.07	2.06
	2.04	2.04	2.06
	2.05	2.05	2.08
	2.05	2.07	2.07
Average	2.05	2.06	2.07
Std Dev	0.006	0.015	0.010
Thickness 30 (mm)	2.03	2.06	2.06
	2.04	2.04	2.07
	2.04	2.04	2.06
	2.03	2.06	2.06
Average	2.04	2.05	2.06
Std Dev	0.006	0.012	0.005

Detergent	Dry Blank	Dry Blank	Dry Blank
Temperature	Ambient	Ambient	Ambient
Visual Appearance 0	White	White	White
Visual Appearance 15	White	White	White
Visual Appearance 30	White	White	White
Hardness 0 Shore A	77	75	77
	76	75	76
	75	75	75
	77	75	74
Average	76	75	76
Std Dev	1.0	0.0	1.3
Hardness 15 Shore A	76	75	77
	75	75	77
	75	75	76
	76	76	77
Average	76	75	77
Std Dev	0.6	0.5	0.5
Hardness 30 Shore A	76	76	75
	75	76	76
	76	76	75
	76	76	75
Average	76	76	75
Std Dev	0.5	0.0	0.5