



8-Day Microbial Challenge of the MaxPlus Positive Flow Connector

LGGS Lab Services of Anaheim, California, an independent laboratory facility, performed an extended microbial study of the MaxPlus Connector for Maximus Medical Products, Inc. The study was performed over an 8-day period of time to simulate clinical scenarios in the hospital and home care environments.

OBJECTIVE: The purpose of this study was to ascertain whether the MaxPlus Positive Flow needleless valve, when microbiologically challenged over an extended (8-day) period of time, maintains a physical barrier to microbial contamination.

TEST METHOD: The experiment utilized artificial contamination of the valve each day, with twelve (12) engagements per 24-hour period for a total of ninety-six (96) engagements over the course of the 8-day study. *Staphylococcus epidermidis*, a common skin bacterium, was selected as the challenge microorganism. Before each engagement the valve was decontaminated with 70% Isopropyl Alcohol. After each engagement, eluate injected through the test system was collected and tested for the presence of the challenge microorganism. The test model selected, in conjunction with artificial contamination, "challenged" the MaxPlus valve under what would be considered a worst case clinical setting.

TEST PROCEDURE: During test preparation, four (4) 1mL aliquots of suspension were incubated for 24 – 48 hours; then harvest cells were centrifuged for 15 minutes. All debris was aseptically removed and serial dilutions were performed to prepare and verify test suspensions. Positive and negative test units were attached to individual sterile filter funnel units and positive/negative controls. The challenge suspension, containing a nominal population of 5.0×10^5 / mL of *Staphylococcus epidermidis*, saturated an applicator tip with sufficient volume to inoculate with 10^3 cfu's / device. Using caution not to activate the unit, the challenge suspension was applied and allowed to set at room temperature for approximately 1-4 minutes. The unit was visually observed for signs of inoculum on the injection site.

Repeated use simulation began by disinfecting each (20) test sample using alcohol prep pads and a standard hospital disinfection procedure (aggressive circular motion with pressure for 3 seconds). 10cc of PBS were aspirated from the flush bag per the manufacturer's instructions. Each unit was fully engaged with separate 10cc PBS filled syringes and the wash was collected in an attached 0.45 micro membrane filter funnel unit. The contents of product wash were pooled, for each unit, into individual sterile filter funnel units.

.After all twelve (12) replicate use simulations had been performed, the test units were aseptically removed from the filter funnel unit. The filter funnel was washed with an equal volume of sterile, PBS. Aseptically the membrane filters were transferred to individual 100 X

15mm SCDA plates using sterile forceps and a rolling motion to avoid air entrapment under the membrane filter. The plates were incubated for a minimum of 96 hours (5 days) at 30-35°C. These steps were repeated for a total of twelve (12) replicate use simulations per unit each day and were thereafter performed for seven (7) additional days to total ninety-six (96) engagements over eight (8) days per test sample.

VERIFICATION: The negative control sample was processed the same as the test units only omitting the challenge microorganism inoculation procedure. The positive control sample was then processed omitting only the disinfection procedure. Following incubation, the colonies were enumerated and recorded. Following test day eight, inoculate population verification and population verification of the samples was performed.

TEST RESULTS: MP1000 – MaxPlus

Day	Number of Test Samples	Test Sample Failures	Negative Control	Positive Control
1	20	0/20	0/1	1/1
2	20	0/20	0/1	1/1
3	20	0/20	0/1	1/1
4	20	0/20	0/1	1/1
5	20	0/20	0/1	1/1
6	20	0/20	0/1	1/1
7	20	0/20	0/1	1/1
8	20	0/20	0/1	1/1

CONCLUSION: The extended microbial challenge test results indicate that, in all cases, the MaxPlus Positive Flow Connector continued to provide a physical barrier to contamination for an eight (8) day period while performing 12 repeat activations per day for a total of ninety-six (96) activations. The study results indicate that the MaxPlus Connector, when using common disinfection protocol and worst case clinical simulation, did not increase the potential for microbial contamination.