

MaxPlus™ 72-Hour Activation Testing

MAXPLUS ACTIVATION TESTING was performed by Medegen MMS, Inc. of Ontario, California. The purpose of this test was to evaluate the performance of the MaxPlus during and after 204 activations, with various liquids administered through it, over a 72-hour period of time.

Specification for Performance Acceptance

The performance specification states that the valve must seal and return to an unactivated state promptly upon disconnection from a male luer. The valve must withstand 204 activations from a standard male luer syringe without degradation of performance over a 72-hour period of time and the valve must return to within 0.010” of flush with the access port top.

Test Protocol

The 10 test samples were activated, with a standard syringe male luer, 68 times per 24 hours for a 72-hour period of time. Various fluids were injected during the activation. Throughout the testing each sample was examined for valve return to specification. Leak testing was performed at 24, 48, and 72-hour intervals.

	<u>Valve Return</u> (During And After 204 Activations Over 72 Hours) ¹	<u>Low Pressure</u> <u>Leak Test (8”</u> <u>Head Height</u> <u>For 2 Hours)</u> ²	<u>Medegen</u> <u>System</u> <u>Pressure</u> (45psi For 30 Seconds) ³
1	Pass	Pass	Pass
2	Pass	Pass	Pass
3	Pass	Pass	Pass
4	Pass	Pass	Pass
5	Pass	Pass	Pass
6	Pass	Pass	Pass
7	Pass	Pass	Pass
8	Pass	Pass	Pass
9	Pass	Pass	Pass
10	Pass	Pass	Pass

Conclusion

The MaxPlus Positive Flow Connector can be activated, with a standard male luer, 204 times in a 72-hour period without any degradation of performance.

¹ Protocol/Directive ENP-029 Rev. N/C; Test# 57560-6

² Q-Test-85 Low Pressure Leak Test

³ Q-Test-77 Medegen System Pressure