

## APPENDIX D - DOWNSTREAM OCCLUSION

### Time to Occlusion

The maximum time for activation of the downstream occlusion alarm at the minimum flow rate of 0.5 mL/hr is 1 hour at the minimum occlusion threshold setting. It is 3 hours at the maximum occlusion alarm threshold setting.

The maximum time for activation of the downstream occlusion alarm at the intermediate flow rate of 25 mL/hr is 50 seconds at the minimum occlusion threshold setting. It is three minutes at the maximum occlusion alarm threshold setting.

### Bolus Volume

The maximum bolus volume generated as a result of operation at 25 mL/hr and reaching the minimum downstream occlusion alarm threshold is 0.25 mL.

The maximum bolus volume generated as a result of operation at 25 mL/hr and reaching the maximum downstream occlusion alarm threshold is 0.8 mL.

---

**CAUTION:** Specifications for Downstream Occlusion detection times and bolus volume, after release of occlusion, are based on specific test conditions. The analytical related conditions are:

- A distance of 48” from the point of the downstream occlusion to the SIGMA Spectrum’s Downstream Occlusion sensor (approximately the distance from the IV administration set’s exit from the pumping channel to the point of occlusion).
- The 48” test administration set contained one “y”-site (no filters, or other components).
- Testing was at the nominal room temperature (72°F ±2°F).

Time to Downstream Occlusion and Bolus Volume release will generally increase under the following conditions: longer distances to the occlusion point, additional fluid volumetric area (from filters or other components within the IV set length) and hotter room temperatures.

---