

APPENDIX B - FLOW RATE ACCURACY

Effect of Fluid Container Height ^{1 2}

The performance of the infusion pump will be influenced by the forces of gravity on the fluid being administered to the patient. When a fluid container is positioned above or below the patient's administration site, pressure forces associated with the fluid's head-height (distance measured from the center of the pumping mechanism to the top of the fluid in the source container) will cause deviations in the nominal specification for device flow rate accuracy. The nominal head-height used for the flow rate specification is 24" (61 cm).

Effect of Back Pressure

Positive back pressure can influence the flow rate accuracy of the infusion. Back pressure equivalent to 300 mmHg may reduce the flow rate causing a deviation in accuracy by -9%. Negative back pressure of -100 mmHg may increase flow rate causing a deviation in accuracy of 7% Hospira and 3% Baxter IV Sets.

Flow Profile

The SIGMA Spectrum Infusion pump has the following start-up flow rate accuracy curve shape associated with stability through time. These graphs represent the variation in flow rate that is recorded from the time the infusion is started to the end of a two hour period. The graph is intended to give a picture of the "general stability" with time of the infusion. The graph is commonly called a "start-up curve". The techniques and methods of test and generation of this graph are as detailed in IEC 60601-2-24, *Medical electrical equipment – Part 2-24: Particular requirements for the safety of infusion pumps and controllers*.

CAUTION: Accuracy

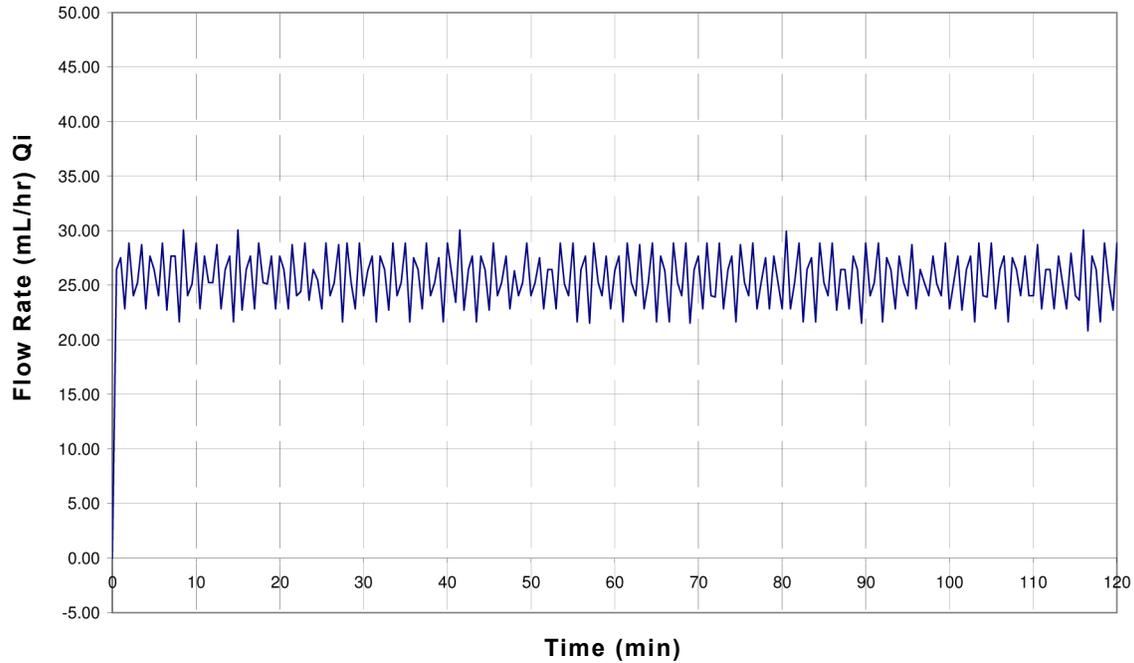
Refer to trumpet curves for flow rate accuracy as a function of short infusion durations.

The upstream occlusion detector may not detect partially occluded tubing. Always check to ensure the IV set's clamp is not closed above the Spectrum Pump and respond appropriately to all primary and secondary check flow prompts.

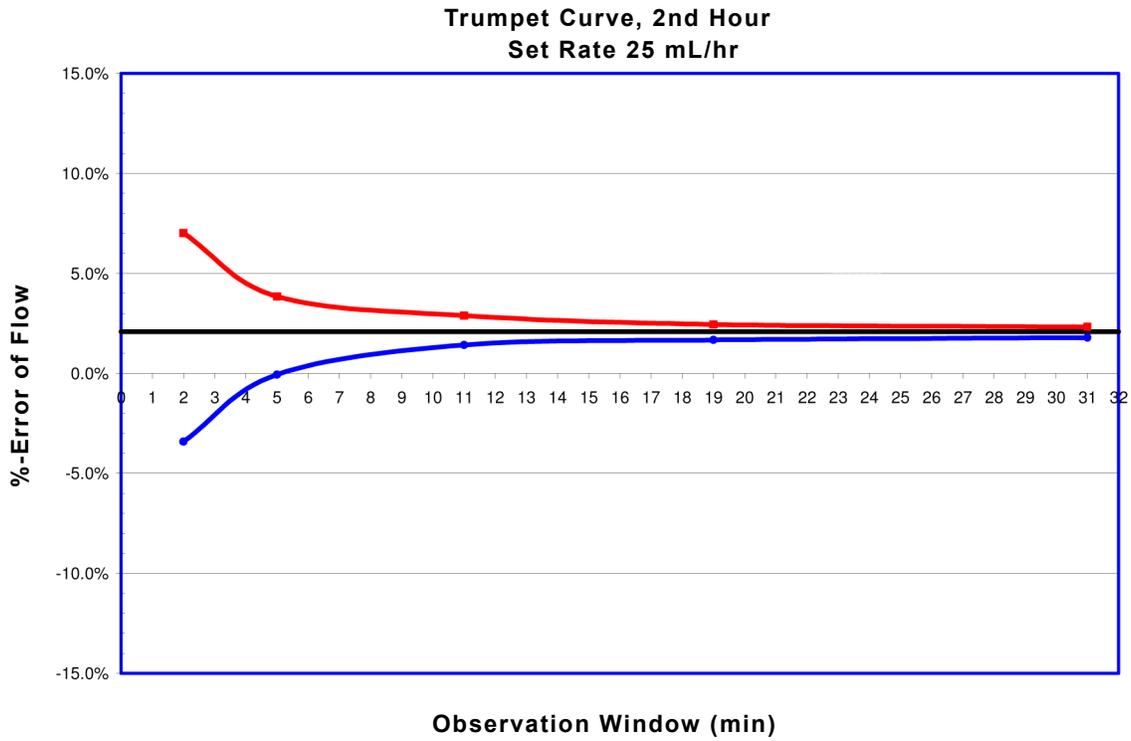
Small bore catheters or needles may cause excessive back pressure at high flow rates. Size the catheters according to expected flow rate and fluid viscosity.

1. REFERENCE: AAMI ID26:1998, SUB-CLAUSE 50.102
2. LIQUID CONTAINER MUST BE VENTED OR A COLLAPSIBLE BAG

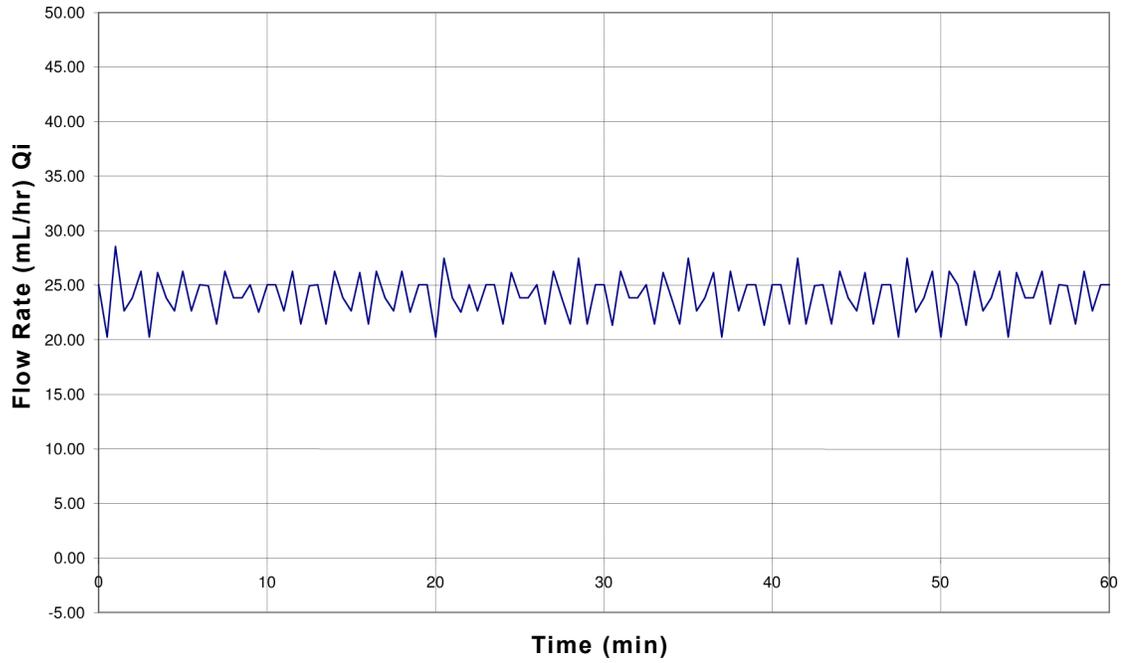
Startup Graph, First Two Hours
Set Rate 25 mL/hr



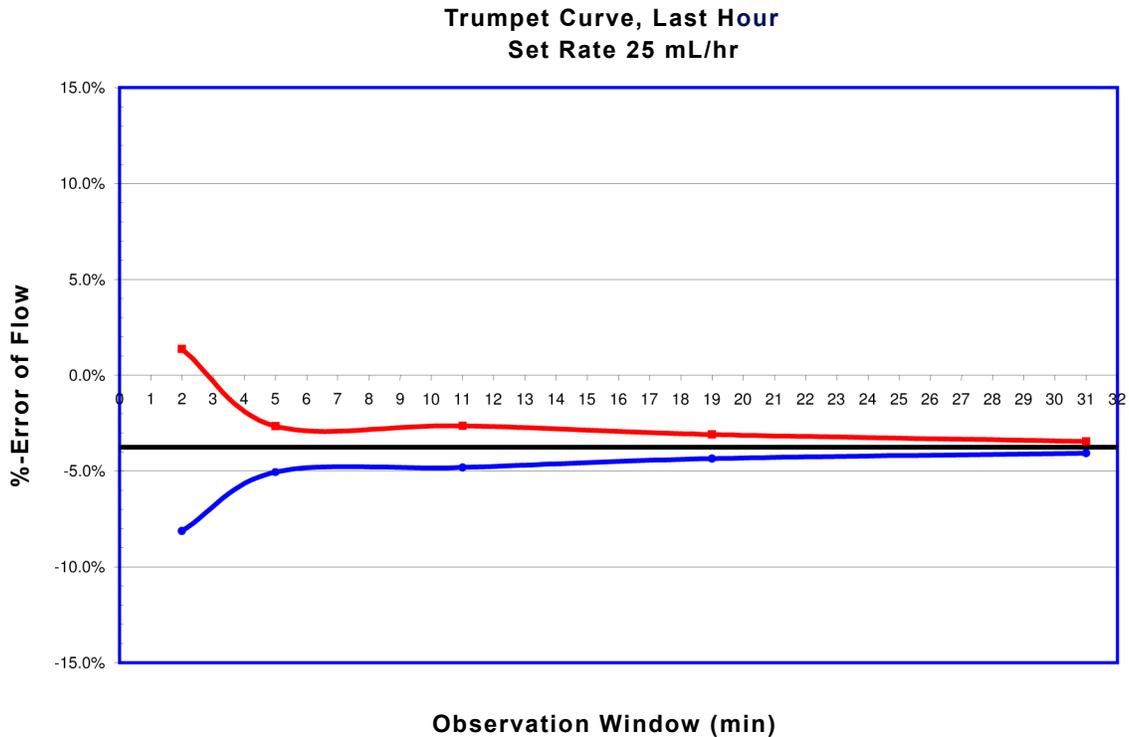
The percent variation of mean flow rate accuracy over a specific observation period may be quantified with the use of a trumpet graph. Using the rationale for development of a statistical trumpet graph as defined in IEC 60601-2-24, a presentation of the SIGMA Spectrum mean flow over a specific measurement interval is provided.



Flow Rate Graph, Last Hour
Set Rate 25 mL/hr



Typical of intermediate rate last* Hr Flow Accuracy



Typical of intermediate rate last* Hr, Trumpet Graph

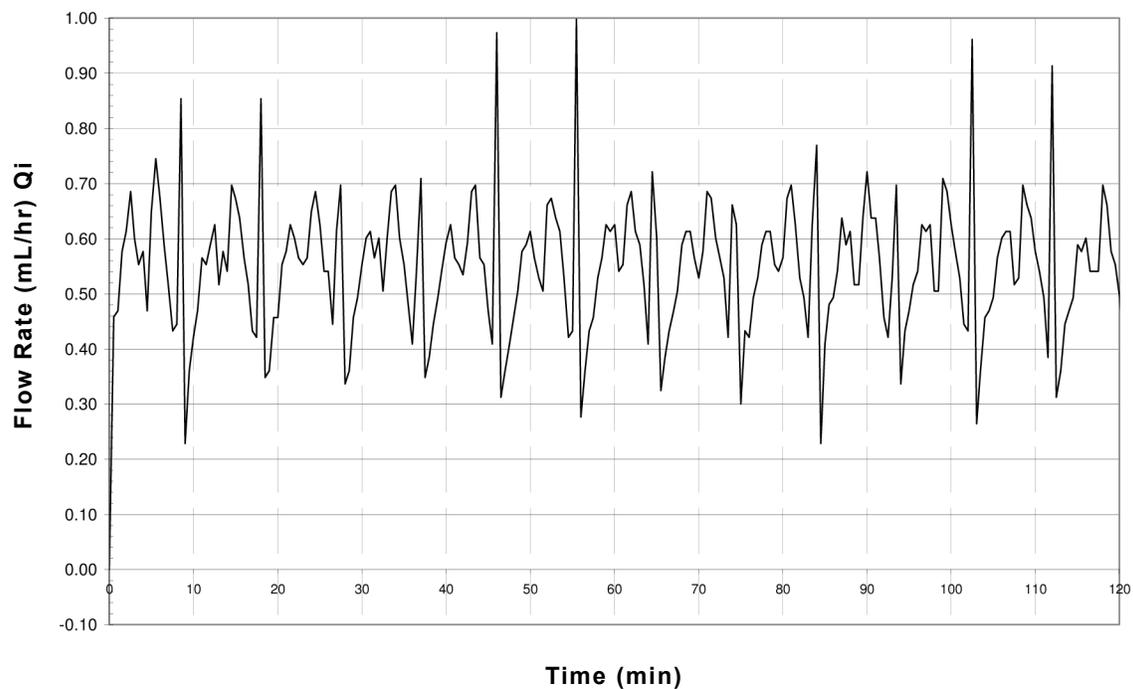
NOTE: For Hospira calibration the last hour is the 72nd hour. For Baxter calibration the last hour is the 96th hour.

It is important for the clinician to understand the pharmacological influence of specific drugs based on concentrations and patient response when used in conjunction with the SIGMA Spectrum.

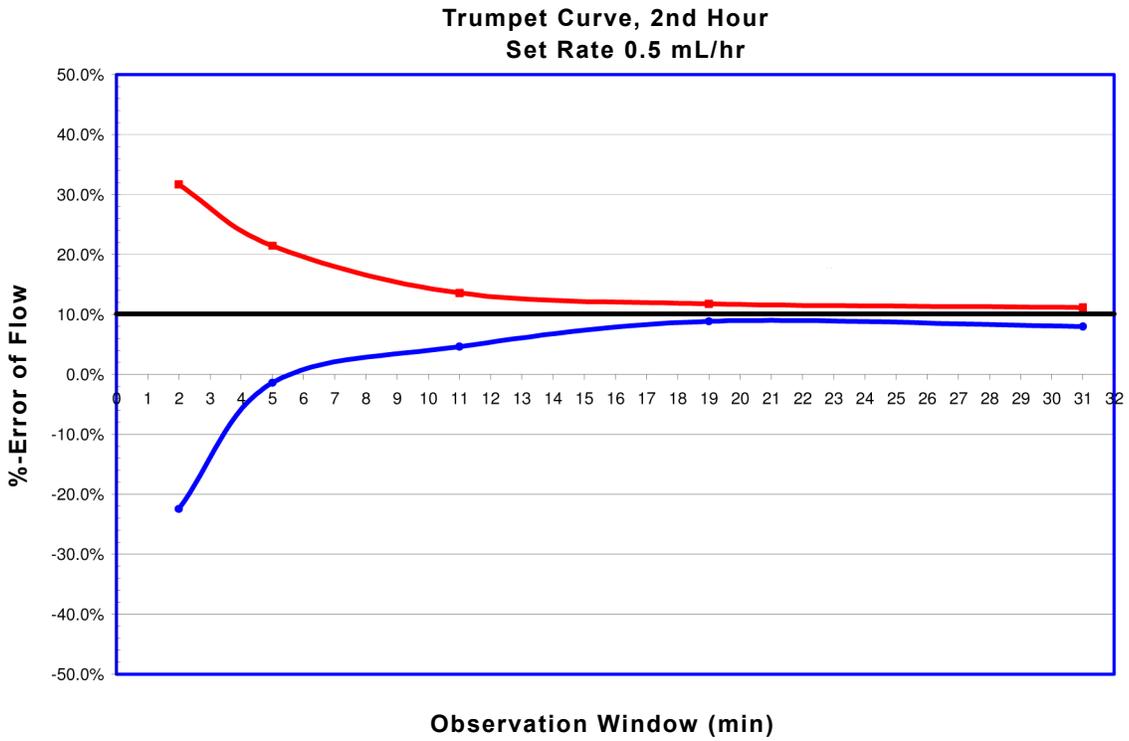
Pumping mechanisms produce fluctuation in fluid flow by design based on the specific mechanism type (peristaltic, piston, rotary, etc.), electronic control system and other factors related to the administration set's characteristics. Specific flow profiles are helpful in determining the correct clinical application for the infusion pump. Data is presented as requested by the applicable standards and represents the typical flow rate function of the Spectrum Pump for short and long term operation. To help with the visualization of the flow inconsistencies that are typical of most infusion pumps, the start-up graphs and trumpet curves are extended to include the minimum rate (.5mL/hr) and intermediate rate (25 mL/hr) for the SIGMA Spectrum.

NOTE: The SIGMA Spectrum is best classified as a "Volumetric Infusion Pump" as defined by the applicable standards. Reference IEC 60601-2-24 and AAMI ID26:1998, Medical electrical equipment – Part 2: Particular requirements for safety of infusion pumps and controllers.

Startup Graph, First Two Hours
Set Rate 0.5 mL/hr

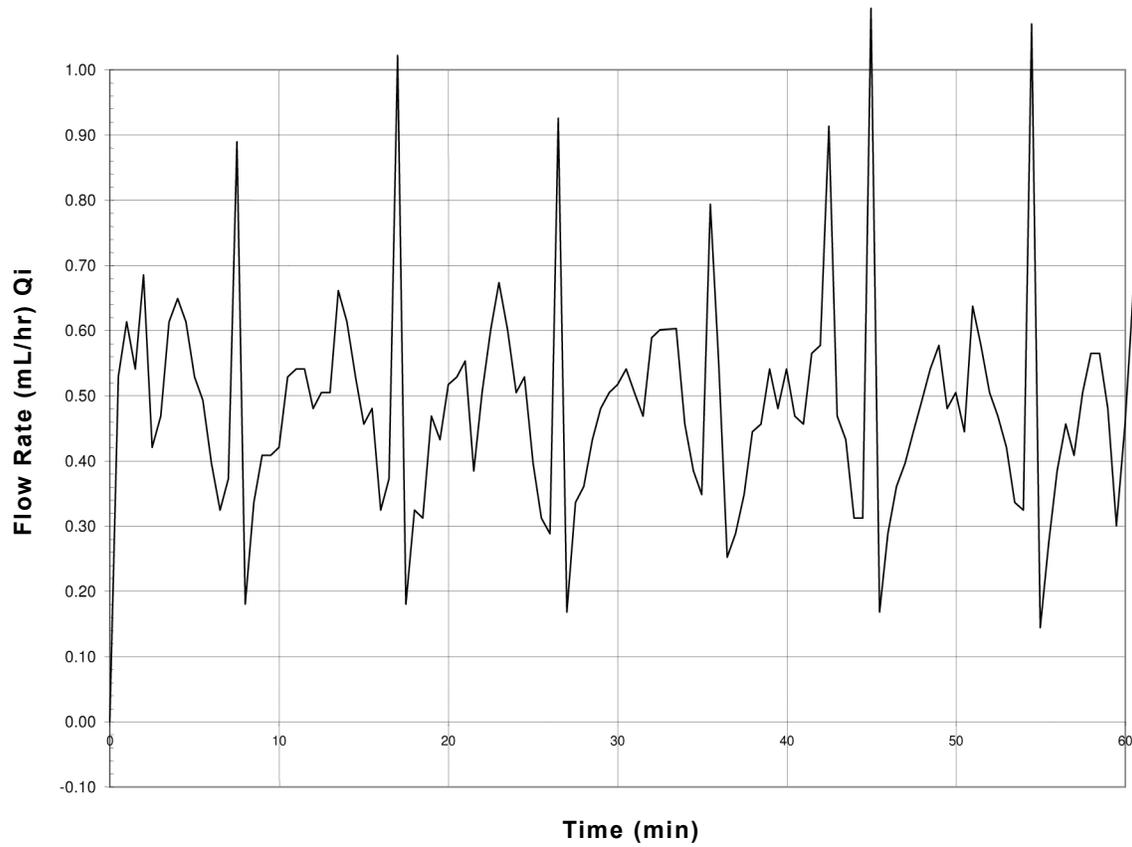


Typical of minimum rate start-up, flow rate



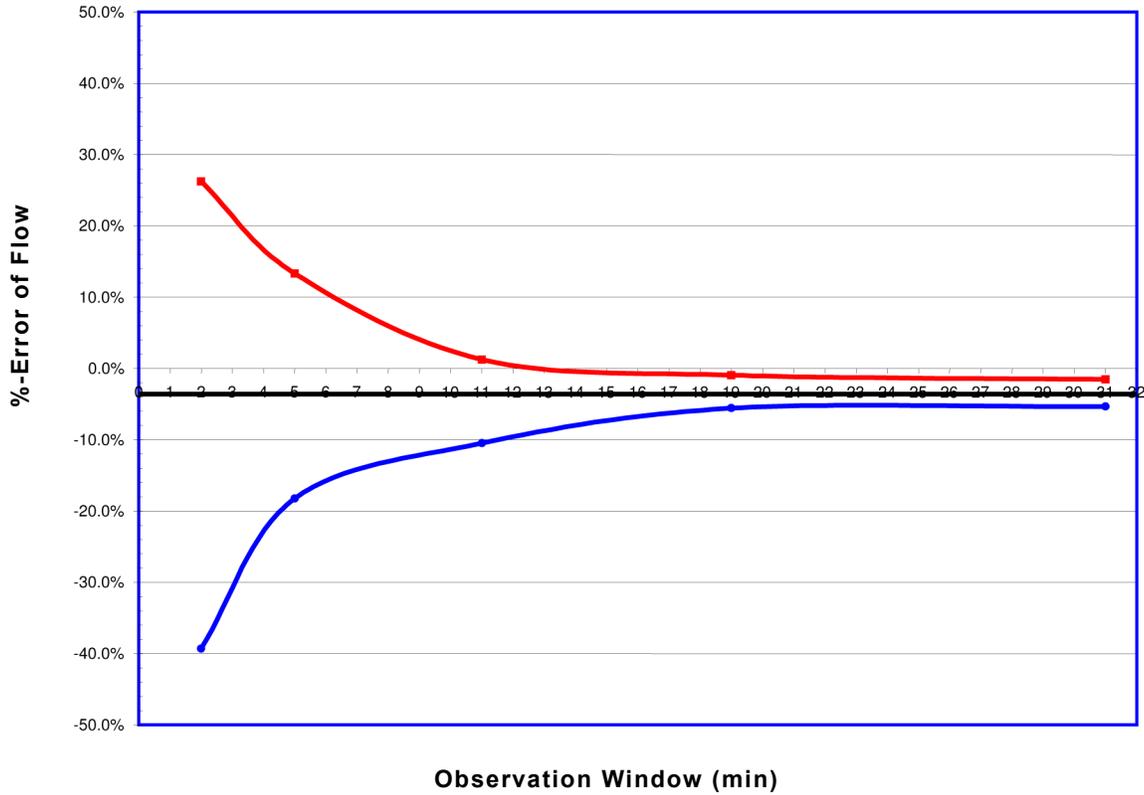
Typical of minimum rate 2nd Hr, Trumpet Graph

Flow Rate Graph, Last Hour
Set Rate 0.5 mL/hr



Typical of minimum rate last* Hr Flow Accuracy

Trumpet Curve, Last Hour
Set Rate 0.5 mL/hr



Typical of minimum rate last* Hr, Trumpet

NOTE: For Hospira calibration the last hour is the 72nd hour.
For Baxter calibration the last hour is the 96th hour.