Medicine Concentration in the AutoStart® Burette following an Automatic Flow Restart Event

Geoff Daly, Operations Manager, Analytica Ltd.

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Abstract: The AutoStart Burette uses a novel system of floats and seals to allow flow from an IV bag to automatically restart without nurse intervention once a medicated bolus has been delivered. The float requires a small residual volume to be present to operate, which means that the flow restarts prior to the entire bolus being delivered. The current analysis uses a technique called computational fluid dynamics to reveal the idealised flow patterns in the AutoStart Burette and determine the theoretical medicine concentrations. Conservative flush volumes are presented for varying flow rates, along with a comparison with standard burettes.

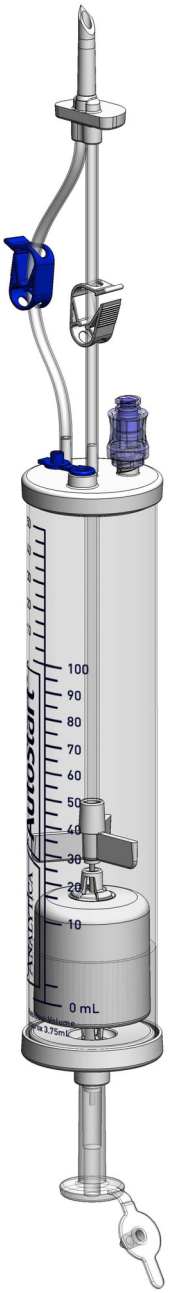

Figure 1: The AutoStart Burette

INTRODUCTION

The AutoStart Burette (Figure 1) is an infusion system component that possesses a novel feature to automatically restart flow from an IV bag once a medicated bolus has been delivered to the patient. This AutoStart function saves clinician's time by not requiring their immediate return to the patient to manually restart the flow.

When a bolus is delivered in a standard burette, the entire volume is allowed to flow out of the device, except for a tiny amount (1-2 mL) of residual fluid which may be left as part of the shutoff valve operation. The standard burette is then flushed through using, say, 50mL of fluid to ensure that medicine delivered in the current dose will not be present, or conflict with, medicine in the next dose.

The AutoStart burette has a system of floats and seals which require that the flow is

restarted from the IV bag before the entire bolus has been delivered.

The volume of fluid present in the burette when the AutoStart function reopens the flow from the IV bag is approximately 10.8mL.

The question many clinicians ask is "What is the flush volume?" which can be rephrased as "How long does it take for the medicine in that residual 10.8mL to leave the burette?"

This paper endeavours to answer that question.

ANALYSIS

Fluid flow rates in burettes typically range from 40mL/hour maintenance flows to 100mL/min challenges. Due to the wide range of flow rates and small volumes of fluid involved in the residual volumes of infusion systems, experimental determination of concentrations in practice would be fraught with difficulty and inaccuracy. An appropriate method of estimating the concentrations in the system with time is to use a numerical method called Computational Fluid Dynamics (CFD).

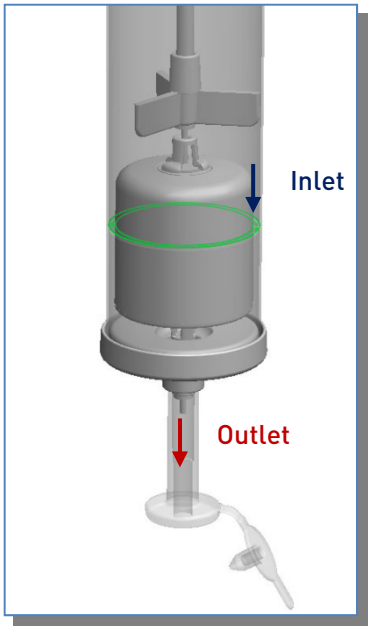

Figure 2: Fluid Geometry

The geometry examined in this CFD analysis is shown in Figure 2, which is taken directly from the 3D engineering model used to generate the plastic parts seen in production burettes.

CFD uses computer modelling to break down the geometry of the fluid into much smaller volumes as shown in Figure 3, and then uses the laws of physics (fluid dynamics) to calculate how these small volumes 'move' and interact with each other over time.

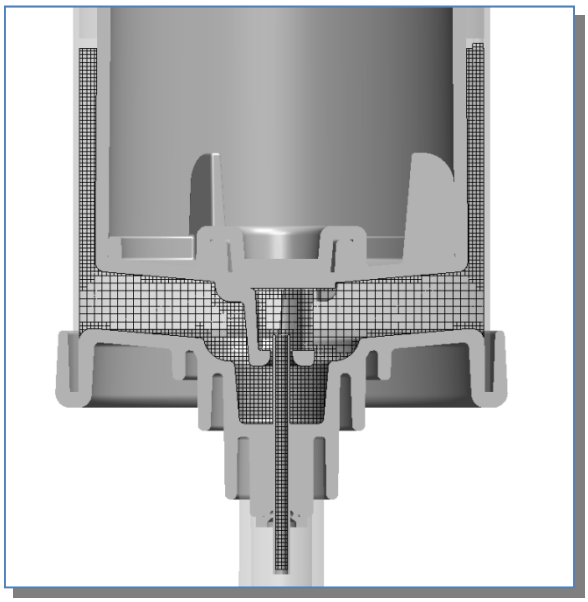

Figure 3: CFD Mesh

There are a large number of solvent-solute combinations of varying concentrations regularly used in infusion systems, so the analysis could not practicably be run for each combination. As such, this analysis uses the physical properties of pure water at room temperature to model the flows. Under the conditions of this analysis, the fluid dynamics properties of pure water are not materially dissimilar to that of 0.9% saline.

The analysis commences with the 10.8 mL volume comprised entirely of "Fluid A" which can be considered to be the medicated solution remaining after most of the bolus has been delivered. In reality, this may represent the remainder of a bolus of 3 mL of medicine mixed with 100mL of saline.

Fluid B (e.g. pure saline from the IV bag) is injected at a single entry point on the top of the fluid volume. This models the flow of fluid over the side of the float once the flow has restarted.

The analysis calculates the concentration of Fluid A in the outlet tube (i.e. the concentration seen by the patient) as well as the

concentration left in the burette as a whole (i.e. how much medicine is left)

The analysis has been run for various flow rates from 40mL/hour to 100mL/min. Each run was terminated only after the total volume concentration of Fluid A had dropped below 10% in order to control computation time.

RESULTS

Plots of Total Concentration and Outlet Concentration for selected flow rates of 100mL/minute, 400mL/hour, and 40mL/hour are shown in Figure 4 and Figure 5 respectively.

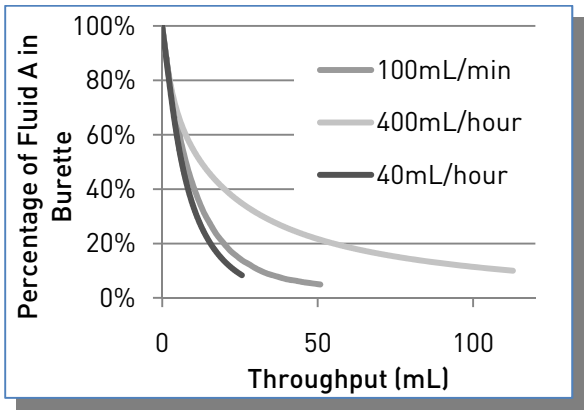

Figure 4: Concentration of Fluid A in burette versus flush throughput for selected flow rates.

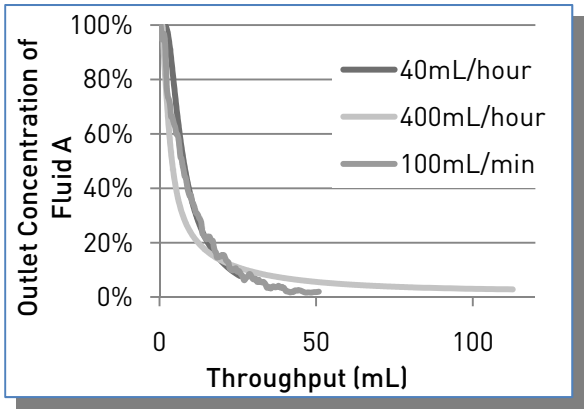

Figure 5: Concentration of Fluid A at the burette outlet versus flush throughput for selected flow rates

It is important to note that the concentrations stated on the vertical axes are not the absolute concentration of medicine in the solution, but are the concentrations relative to the initial concentration when the AutoStart function began.

Figure 6 to Figure 8 show the streamline flow patterns in the fluid volume at the three selected flow rates.

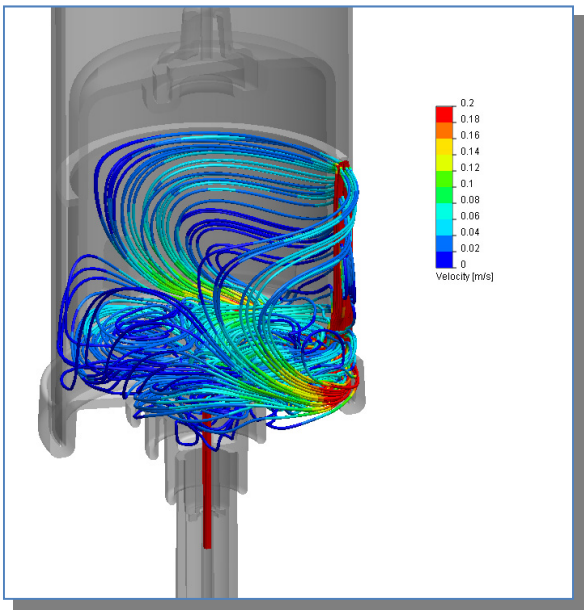

Figure 6: Streamlines for 100mL/min Flow

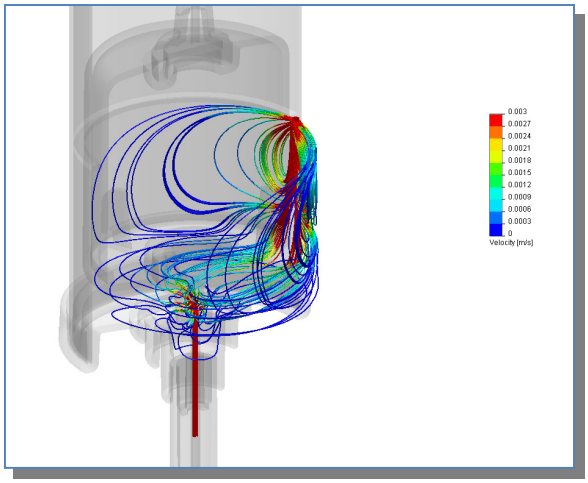

Figure 7: Streamlines for 400mL/hour Flow

Table 1 shows the amount of fluid required and the time taken, from the AutoStart flow restart, for 90% of the medicine remaining in the burette at that time to leave the burette.

This table data is displayed graphically in Figure 9 and Figure 10.

The table and figures includes data from all of the flow rates analysed.

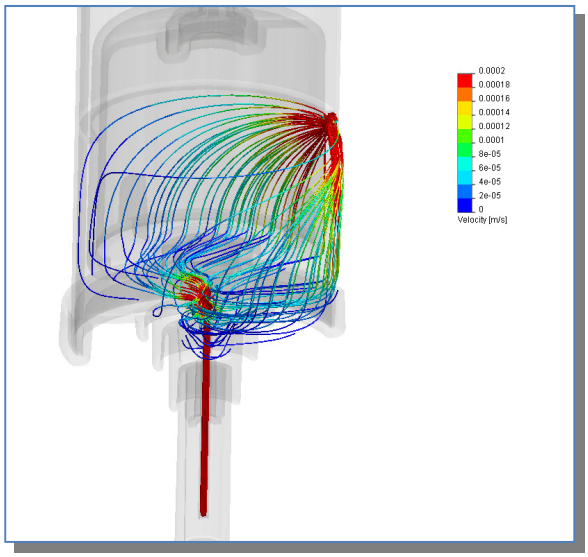

Figure 8: Streamlines for 40mL/hour Flow

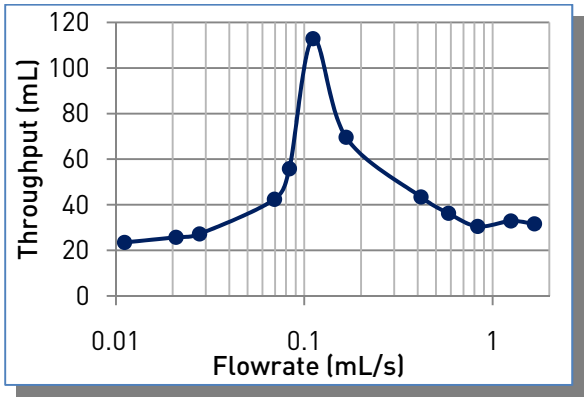

Figure 9: Throughput required to reach 10% Fluid A in burette (from Table 1)

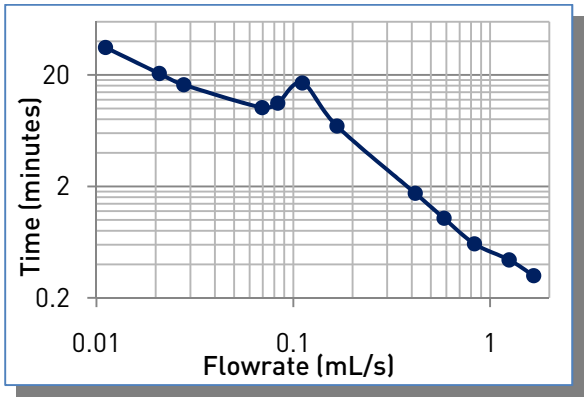

Figure 10: Time to reach 10% Fluid A in burette (from Table 1)

Table 1: CFD-modelled flush throughput and time needed to reach a total concentration of 10% Fluid A in the AutoStart burette at various flow rates.

Flow rate	Flow rate (mL/s)	Flush Through-put (mL)	Time (mm:ss)
40 mL/hour	0.011	23.51	35:16
75 mL/hour	0.021	25.75	20:36
100 mL/hour	0.028	27.22	16:20
250 mL/hour	0.069	42.42	10:11
300 mL/hour	0.083	55.81	11:10
400 mL/hour	0.111	112.84	16:56
10 mL/min	0.167	69.63	06:58
25 mL/min	0.417	43.43	01:44
35 mL/min	0.583	36.25	01:02
50 mL/min	0.833	30.53	00:37
75 mL/min	1.250	32.88	00:26
100 mL/min	1.667	31.63	00:19

DISCUSSION

Explanation of prolonged evacuation at medium flow rates.

The most striking feature of Figure 9 and Figure 10 is the unusually slow reduction in Fluid A concentration when the flow rate is near 400mL/hour.

Possibly the best explanation can be found from the streamline plots of Figure 6 to Figure 8.

Figure 6 shows the very high 100mL/min flow rate, and as expected, this has strong mixing due to the turbulent flow.

In contrast, the slow 40mL/hour flow shown in Figure 8 is an orderly progression of the fluid from inlet to outlet. This is to be expected with approximately laminar flow.

Figure 7, representing 400mL/hour is intermediate and has a large loop of recirculating flow that causes some streamlines to be up to twice as long as those in the laminar flows. This results in a longer medicine residency than expected, shown as a 'bump' in the figures. The extended residency results are a combination of a) the geometry of the burette, b) the flow rate making the flow transitional (i.e. neither laminar nor fully turbulent), and c) idealisation limitations in CFD as discussed below,

Limitations of the CFD Analysis

CFD analysis uses an idealised model of the burette flow. In the current model the following approximations of reality are made:

1. The float remains completely stationary. In reality, the float will move up and down slightly and also spin around its axis. This will assist the mixing of fluids A and B.
2. The fluid inlet is modelled as a single, stationary inlet of fixed size and shape. In reality, the inlet flow will move around the periphery of the float, and there may be multiple inlet 'streams' falling over the float sides into the fluid body. This would mean that there would be less likelihood of pockets of the medicated fluid avoiding the influx of the incoming IV fluid for extended periods.
3. There are no external inputs. In reality there will be vibration and gross movement from nurses and patients interaction with the infusion line. This will affect the fluid in the system as it will tend to increase mixing.

The net effect of these CFD limitations is that the model is conservative. Recirculating pockets such as those shown in the 400mL/hour analysis would be less likely to survive for extended durations due to 'real life' mixing mechanisms.

In real burettes, the recirculating flows near 400mL/hour would not survive as long, and the throughput hump seen in Figure 9 would not be as pronounced.

Medicine delivery in the AutoStart burette compared with a standard burette.

Many clinical readers will want a pragmatic answer as to what difference will the AutoStart feature make to the delivery of their drug.

Consider the following example:

A nurse wishes to give a patient 3ml of drug mixed with 100mL of IV fluid at a rate of 100mL/hour.

With the AutoStart Burette, the nurse fills the burette to the 100mL mark, adds the drug and allows the solution to flow to the patient. There is approximately 106.75mL of this medicated solution (Fluid A) present at this time. 100mL of IV fluid, 3.75 mL residual volume, and 3 mL drug. The residual volume is the amount of fluid remaining in the burette when the float drops and shuts off flow to the patient, for example when the IV bag runs dry. The concentration of the drug in this Fluid A solution is thus 3/106.75 = 2.81%.

The point at which the float system will automatically restart flow from the IV bag is when the fluid level reaches approximately the 8mL mark on the burette scale. At 100mL/hour the fluid will take (100+3-8)*60/100 = 57minutes to drop from the 103mL mark to the 8mL mark.

There will be approx 10.8 mL of solution left in the device: ~8mL on the scale + 3.75 mL residual.

The concentration of the drug in the burette prior to the float opening will still be 2.81%, and there should be 10.8/106.75 = 10.1% of the original 3mL of drug remaining in the burette to be delivered.

Once the float resumes flow from the IV bag, the drug will continue to be delivered to the patient, albeit in the decaying fashion shown in Figure 4.

A standard burette will deliver the 103mL of drug solution at the set rate until the burette is empty.

The performance for a 100mL/hour flow is illustrated in Figure 11. Several features are apparent:

1. For the majority of the bolus delivery, the AutoStart and Standard burettes are nearly identical. The slight variations in slope of the delivery curves is caused by the residual 3.75mL in the AutoStart burette.
2. The main difference, and the topic of this paper is the 'hockey stick' shape of the drug delivery curve in the last 8mL of drug delivery. It can be seen that the AutoStart burette does take longer to deliver the last few percent of the drug.
3. The red curve shows that once the bolus is delivered, most standard burettes will shut-off and the flow to the patient is halted. In the example shown, the delay is 5 minutes, but

this could realistically be any duration where the patient is not receiving treatment.

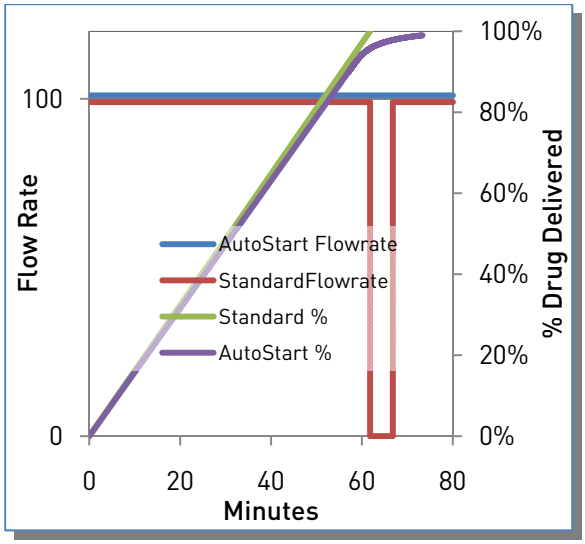

Figure 11: Performance of AutoStart vs Standard burette at 100mL/hour flow.

Table 2: Time taken to deliver a 100mL IV + 3 mL drug solution.

Flowrate	AutoStart time to 99% delivery	Standard time to 100% delivery	Difference
	hh:mm:ss	*hh:mm:ss*	*mm:ss*
40mL/h	02:57:46	02:34:30	23:16
75mL/h	01:36:36	01:22:24	14:12
100mL/h	01:13:20	01:01:48	11:32
250mL/h	00:32:59	00:24:43	08:16
300mL/h	00:30:10	00:20:36	09:34
400mL/h	00:31:11	00:15:27	15:44
10mL/min	00:16:28	00:10:18	06:10
25mL/min	00:05:32	00:04:07	01:25
35mL/min	00:03:45	00:02:57	00:48
50mL/min	00:02:31	00:02:04	00:27
75mL/min	00:01:42	00:01:22	00:20
100mL/min	00:01:16	00:01:02	00:14

Performing a similar analysis on the other flow rates examined in this study, Table 2 shows the differences in time between a standard burette shut-off, and an AutoStart burette delivering ~99% of the drug.

CONCLUSION

- All things being equal, the AutoStart Burette delivers a medicated bolus to the patient slower than a standard burette, but provides continuous treatment.
- Equivalent delivery can be achieved simply by slightly increasing flow.
- If rapid 100% delivery required, use in standard mode and flush one or more times.
- It is always the clinician's decision as to decide what is important in a particular situation – continuous delivery or rapid delivery.
- Further experimental work must be done to validate these results.

ACKNOWLEDGEMENTS

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REFERENCES

[1] ISO 8536-5: 2004 Infusion equipment for medical use — Part 5: Burette infusion sets for single use, gravity feed