

Patients with residual chemotherapy when using 5-FU + saline elastomeric devices.

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Background

Patients being treated with infusional fluorouracil were returning to the hospital with a fluctuating residual volume in their infusor device. Elastomeric devices are designed primarily for increased convenience and mobility, and require no programming as they deliver the drug solution at a predetermined rate over a specified time. The nominal flow rate specifications were based on glucose, as normal saline has a 10% faster infusion rate documented.

All elastomeric devices are prone to a potential plus or minus 10% variation in infusion rate, depending on several factors:¹

Clamped or kinked lines
Temperature
Positioning of the device
Viscosity
Catheter Size
Vein Patency
Air Bubbles
Concurrent infusions via Y-site or 3-way tap
Extension Sets

Picture1–reference1

Folfusor



Specifications

Name	SV2.5	SV0.5	SV5
Code	2C4711K	2C4700K	2C4705K
Nominal Infusion duration	2 days	7 days	1 Day
Nominal Flow Rate	2.5 mL/h	0.5 mL/h	5 mL/h
Nominal Fill Volume	120 mL	84 mL	120 mL
Nominal Temperature	33.3°	33.3°	33.3°
Flow Rate Accuracy	+/- 10%	+/- 10%	+/- 10%
Acceptable Flow Times	43.4-53.2 hrs	153.4-186.2 hrs	21.49-26.40 hrs

Aim

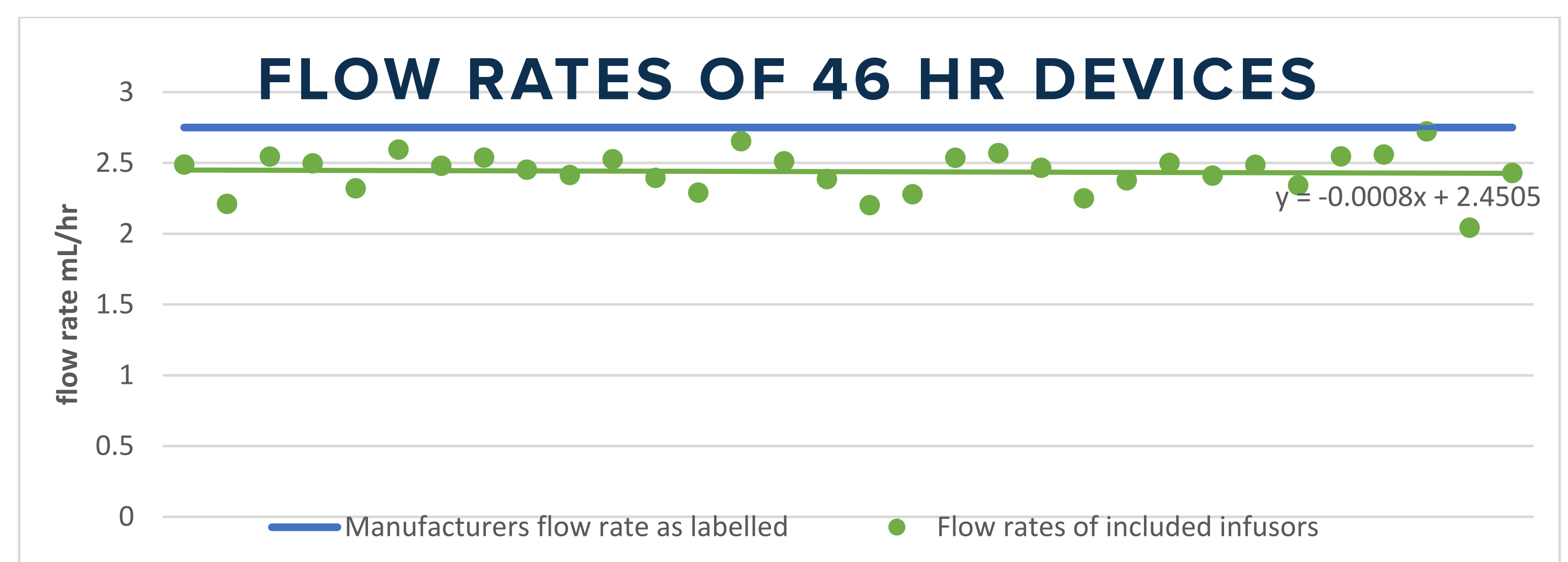
To facilitate the collation of accurate data to address concerns with infusion rate variance with the product manufacturer.

Method

A data collection template was created for nursing staff to conduct the audit over two weeks to capture all relevant information for patients connected to an elastomeric infusor. The template included connect and disconnect times and weights of the 46hr, 96hr and 168hr devices.

Results

A total of 36 devices were recorded from the same manufacturer. Infusors with positive rate variance outside the expected +/-10% tolerance was 31.9% (n=15). The overall average infusion rate variance for those patients who returned with some volume remaining in the device was 10.97%.



Audit Period 07/08/17 - 18/08/17		
Total Number of Infusors Released by Pharmacy	47	
Total Number of Infusors Recorded in Audit	36	76.60%
Total Number of Infusors Missing from Audit	11	23.40%
Total Number of Recorded Infusors Empty on Disconnect	5	13.89%
Total Number of Recorded Infusors with Volume Remaining at Disconnect	31	86.11%
Percentage of Total Infusors with confirmed Positive Variance > 10%	15	31.91%
SV2.5	14	29.79%
SV0.5	1	2.13%
LV2	0	0.00%
Percentage of Total Infusors with Variance within the +/- 10% Product Tolerance	16	34.04%
SV2.5	13	27.66%
SV0.5	2	4.26%
LV2	1	2.13%
Percentage of Total Infusors with Unknown Variance	16	34.04%
SV2.5	11	23.40%
SV0.5	3	6.38%
LV2	2	4.26%
Average Rate Variance for Infusors with Volume Remaining at Disconnect		10.97%
SV2.5		7%
SV0.5		11.49%
LV2		8.85%

Conclusion & Practice update

Results of the audit were forwarded to the manufacturer for further discussion around their guidelines to potentially retest the flow rate of fluorouracil with normal saline.

The manufacturer has reviewed devices in early 2018, measuring specific gravity of normal saline with fluorouracil and concluding it reflects that of glucose.² They will reduce their total fill volumes across the range of devices, meaning that patients will not have any remaining volume at the conclusion of their infusion.

Device Code	Duration	Current Fill Volume	New Fill Volume
SV0.5	7 days	92ml	84ml
SV2.5	2 days (48 hours)	132ml	120ml
SV2.5	46 hours	126.50ml	115ml