

SimplFusor Elastomeric Pump

Minimum and Maximum Fill Volumes

The SimplFusor Elastomeric Pump (Long infusion time article) is intended for continuous infusion of medications for general infusion use including pain management.

- Route of administration: intravenous and subcutaneous

The SimplFusor Elastomeric Pump (Short infusion time article) is intended for continuous infusion of medications for general use including antibiotic delivery.

- Route of administration: intravenous

The SimplFusor Elastomeric Pump (Chemotherapy article) is intended for continuous infusion of medications for chemotherapy.

- Routes of administration: intravenous and intra-arterial¹

The SimplFusor Elastomeric Pumps are recommended to be filled to their nominal volume according to the product labeling. When filled to the nominal volume, flow rate accuracy is within +/- 15% of the nominal (label) flow rate (at 99% confidence level) when delivering normal saline at 88 °F (33 °C).¹

The following information has not been approved by the FDA.

As it may sometimes be necessary to under or overfill an elastomeric pump, testing was performed on the portfolio to determine the minimum and maximum fill volumes while maintaining +/- 15% flow rate accuracy.

The representative samples utilized for minimum and maximum fill volume testing are shown in the table below.² The samples selected were designed to cover all pump sizes that allow under and overfill (50 mL – 400 mL nominal volume) and flow rates (short and long duration) to represent the full portfolio of products.

Representative Samples for Minimum /Maximum Fill volume Testing ²

Model		50-50-60	C100-2-50h	250-250-60m	270 -10-27h	400-100-4h
Reference		481033	484010	481050	480040	481100
Fill Volume tested	UnderFill	40mL	80mL	200mL	240mL	240mL
	Nominal	50mL	100mL	250 mL	270mL	400mL
	OverFill	85mL	150mL	-	-	-

Based on the results of this evaluation, it was determined that the flow rate accuracy of the device was maintained within +/- 15%.

Conclusion

The SimplFusor are recommended to be filled to their nominal volume according to the labelling. However, if under or over fill is necessary, the actual fill volume of each model shall not exceed the min/max limit identified in the table below (based on the nominal volume).

Minimum and Maximum Fill Volumes²

Nominal Volume	50 ~ 60mL	100 ~ 125mL	200 ~ 250mL	270 ~ 400mL	500mL
MIN Fill Volume	40mL	80mL	200mL	240mL	500mL
MAX fill Volume	85mL	150mL	250mL	400mL	500mL

Actual infusion times may vary when choosing to under or overfill an elastomeric pump. Filling the device less than the nominal volume generally results in slower flow rate and filling the device more than the nominal volume generally results in faster flow rate. Use of the elastomeric pump at nominal fill volumes is recommended for optimal performance.¹

References:

1. SimplFusor Elastomeric Pump IFU.
2. Epic Medical Ltd. Internal Data on File.