

SimplFusor Elastomeric Pump Storage after Filling

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 its 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). Infusions should be started within 1-8 hours after filling the device. The performance and safety of the device is validated based on infusion time and an additional 8 hours drug/device contact time.¹

The following information has not been approved by the FDA.

As it may sometimes be necessary to store the SimplFusor Elastomeric Pump after filling and prior to use, testing was performed to ensure that the flow rate accuracy after extended storage of the filled product at both room temperature and under refrigeration, remained within +/- 15% of the nominal flow rate.

Representative samples of the portfolio were tested for flow rate accuracy after extended storage of filled devices as shown in the table below.² The samples selected were designed to cover all pump sizes and flow rates (short and long duration) to represent the full portfolio of products.²

Representative Samples for Flow Rate Accuracy Testing² after Extended Storage²

REF	Volume	Flow	Duration
480010	60mL	5mL/h	12h
481050	250mL	250mL/h	60min
481170	500mL	20mL/h	25h

All pump samples were filled with 0.9% Sodium Chloride to its nominal volume. After filling, samples from each model were randomly selected for flow rate testing to represent the baseline flow rate accuracy (Day 0). The remaining pumps were randomly separated into two groups and stored either under refrigeration (2-8°C) or at room temperature (20-25°C) for 28 days. Flow rate testing was performed on all samples at the end of the storage period (28 days) as well as at selected intermediate time points. Pumps stored under refrigeration were transferred to room temperature 8 hours before flow rate testing was performed.²

Based on the results of this evaluation, it was determined that the flow rate accuracy remained within +/- 15% of the nominal (label) flow rate, when stored after filling to nominal volume, for up to 28 days at either room temperature (20-25°C) or under refrigeration (2-8°C). The pump flow rate trended downward with increasing storage duration, however the flow rate decrease was less for devices stored under refrigeration, as compared to those stored at room temperature. Refer to Exhibit 1 for graphical representations of the accuracy over the storage time.

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.

Exhibit 1: Storage time effect on device accuracy

Figure-1 Summary Results of REF 480010 (Volume 60ml, Flow 5ml/h, Time 12h)

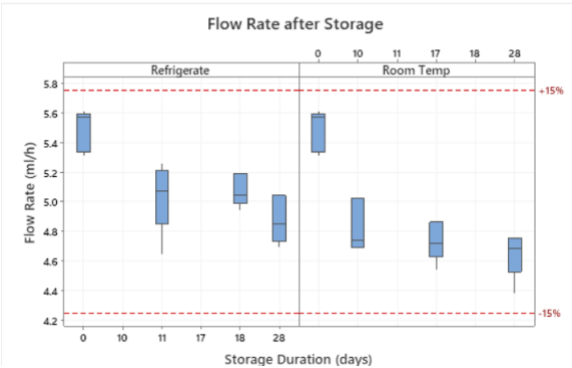


Figure-2 Summary Results of REF 481050 (Volume 250ml, Flow 250ml/h, Time 60min)

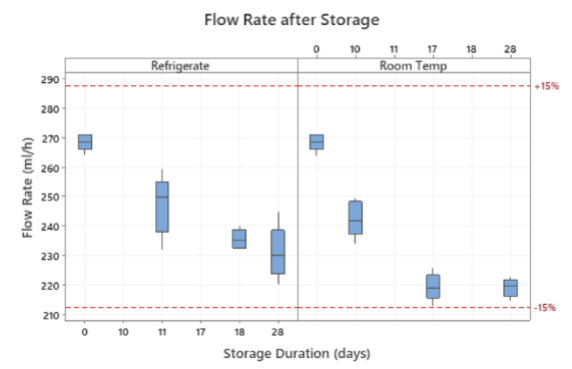


Figure-3 Summary Results of REF 481170 (Volume 500ml, Flow 20ml/h, Time 25h)

