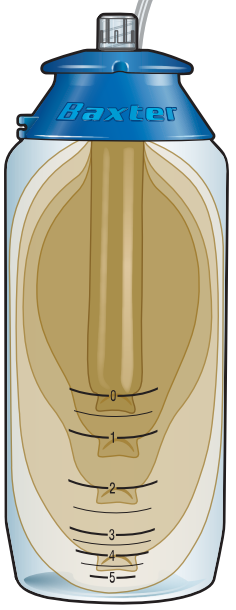
Infusor
AMBULATORY SYSTEMS

Baxter

TECHNICAL BULLETIN

Closed System



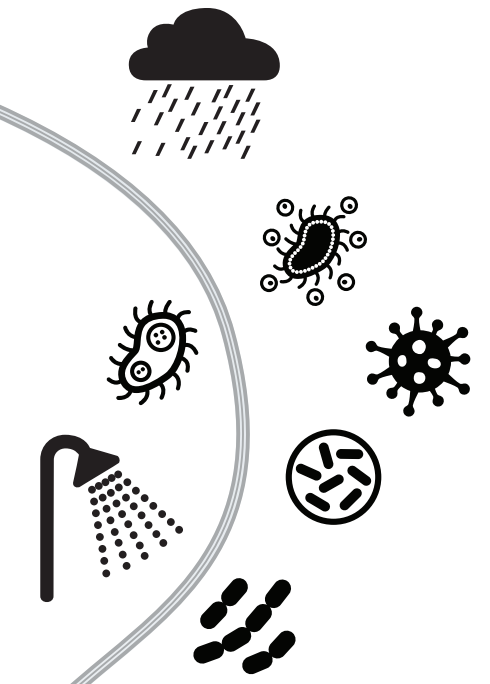
The elastomeric pump with a closed, water-tight administration line

Baxter's Infusor design considerations focus on the product efficacy as well as the patient safety and convenience to enable successful hospitalization at home.
ISO standard 28620 of non-electrically driven portable infusion devices highlights that:

- All elements of the device designed to receive the drug shall constitute a **closed, water-tight system.**[1]
- If applicable, **an air filter should be sealed or kept out of the water**.[1]
- In addition: externally vented open infusion containers increase **the risk of infusate related bloodstream infections** to patient.[2]

Baxter's elastomeric devices are designed to be worn by ambulatory patients receiving infusions that last 30 minutes to 7 days:

- **The absence of a venting air filter** on the administration line of Baxter's ambulatory infusion device is **designed to prevent microbial ingress or potential leaks due to a compromised air vent.**[3]
- **The location of the particulate matter filter** provides end users with a **closed, water-tight administration line**.[3]
- In addition, during that period of time, Baxter's infusor offers **the possibility for the patient to take a shower** by placing the device in a plastic bag or on a flat surface outside the shower/bath.



The administration line is free of air filter.

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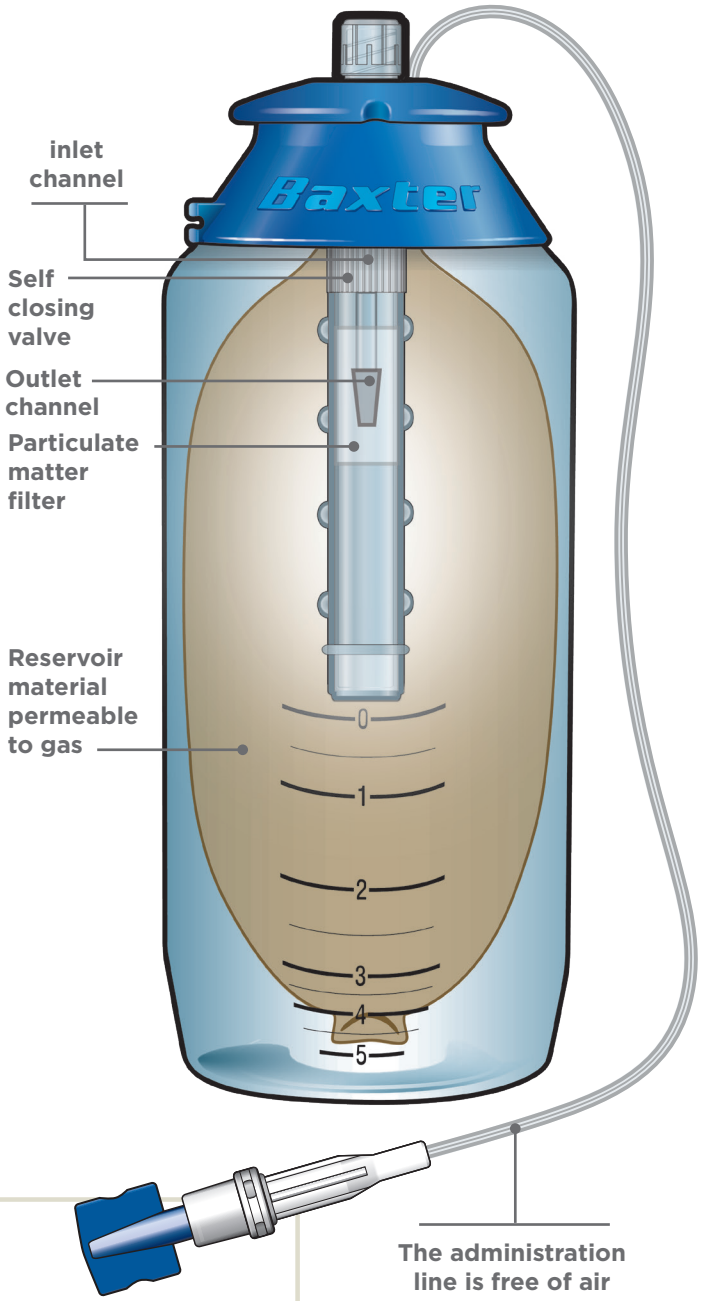
Baxter's elastomeric pump is an ambulatory, disposable device designed to enable intravenous infusion in the home environment.

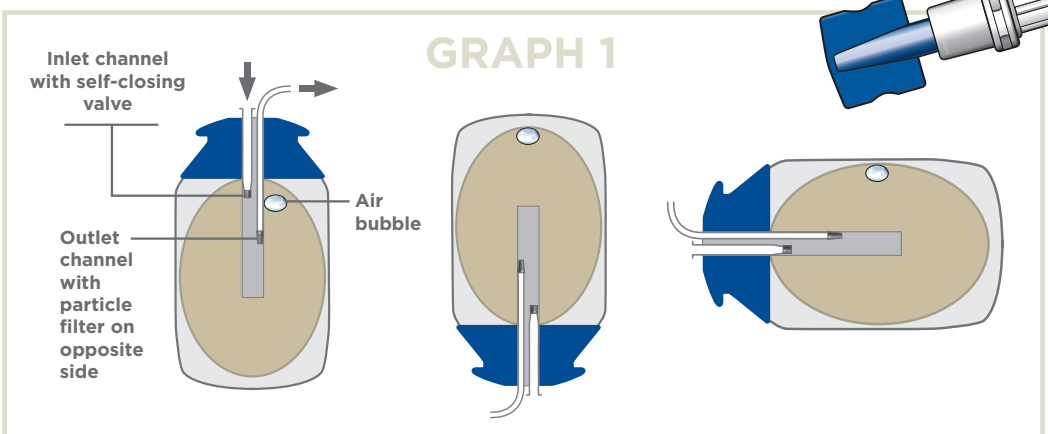
In Baxter's elastomeric pump, **the administration line is free of air filter**. Air management is addressed through the following features:

- **The inlet channel and the outlet channel are separate preventing potential air coming from the inlet channel to enter the outlet channel.**
- The presence of an air bubble (pea size) in the reservoir after the filling process is normal. The entrance of the outlet channel is designed at the centre of the reservoir. **The law of gravity then limits the probability for the air bubble to enter the administration line** (see Graph 1).
- **Air in the reservoir will disappear after several hours** as the reservoir material[4] is permeable to gas.

Additional considerations:

- The particulate matter filter is ISO compliant and sealed upstream, inside the reservoir, on top of the outlet channel.
- The administration line is kink resistant.
- The administration line can be secured around the pump head.





REFERENCES: **1.** ISO 28620:2010, Medical devices - Non-Electrically driven portable infusion devices, 2010-02-15, p4 **2.** Impact of switching from an open to a closed infusion system on rates of central line – associated bloodstream infection: A meta-analysis of time-sequence cohort studies in 4 countries; Maki, Rosenthal, et al; 2011 **3.** Data on file **4.** Baxter's elastomeric material is a unique proprietary formulation of four ingredients where the main ingredient is a polyisoprene rubber supplied by Goodyear.

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