

ELASTOMERIC INFUSION SYSTEMS: SAFE AND EFFICIENT ADMINISTRATION



OHP-014

Arranz Castella T, Marquez Peiró JF, Jimenéz Torres J, Gaspar carreño M, Moreno Diaz R,
Gorgas Torner MQ
Material Devices Group SEFH Spain

BACKGROUND

Elastomeric infusion systems or infusers have been in use in clinics for more than twenty years. The development of these systems has been a significant advance in the administration of drugs in certain clinical situations, both for outpatients and inpatients. Maintaining a stable plasma concentration of a drug enables greater control of an illness and its symptoms and it improves patients' quality of life when good integration into patients' everyday lives is observed.

There are many infusion systems on the market. In some cases, these differ in management principles, but notably in their elastomer composition. All of these factors mean that each infuser can be used to administer different drugs. In the case of 5-fluorouracil (5-FU), it has been shown that administration by continuous infusion is more effective and has fewer adverse effects when these infusion systems are commonly used. However, many studies show differences in the precision of infusion rate due to factors such as 5-FU concentration, temperature, diluents, etc. Patient behavior and lifestyle are also potential safety factors and it is important to adequately train patients on how to manage the infuser correctly.

PURPOSE

Provide general recommendation in the use of elastomeric infusion devices for oncologic patients with continue infusion of 5-fluorouracil (5-FU) in order to provide an effective and safe way of administering the medication to the outpatient.

MATERIALS AND METHODS

Revision of the technical specifications for all the infusion devices available in the market, as well as review of the research and studies currently available that show differences in the accuracy of infusion speed. These differences are due to factors in the infusion itself (concentration, diluent agent, etc.) and to factors related with the behaviour and life style of the patient.

The sources of the information are the following:

- 1) Technical datasheets of the different infusion devices Autofuser, Vessel Fuser, Folfuser, Surefuser, Accufuser and Dosi-Fuser
- 2) Information from healthcare Products "Medical devices": Advise to patients
- 3) Bibliographic research in PubMed using the key words "elastomeric infusion devices" AND "5-FU infusion" and the resources available through the SEFH Website (Spanish Association of Hospital Pharma)

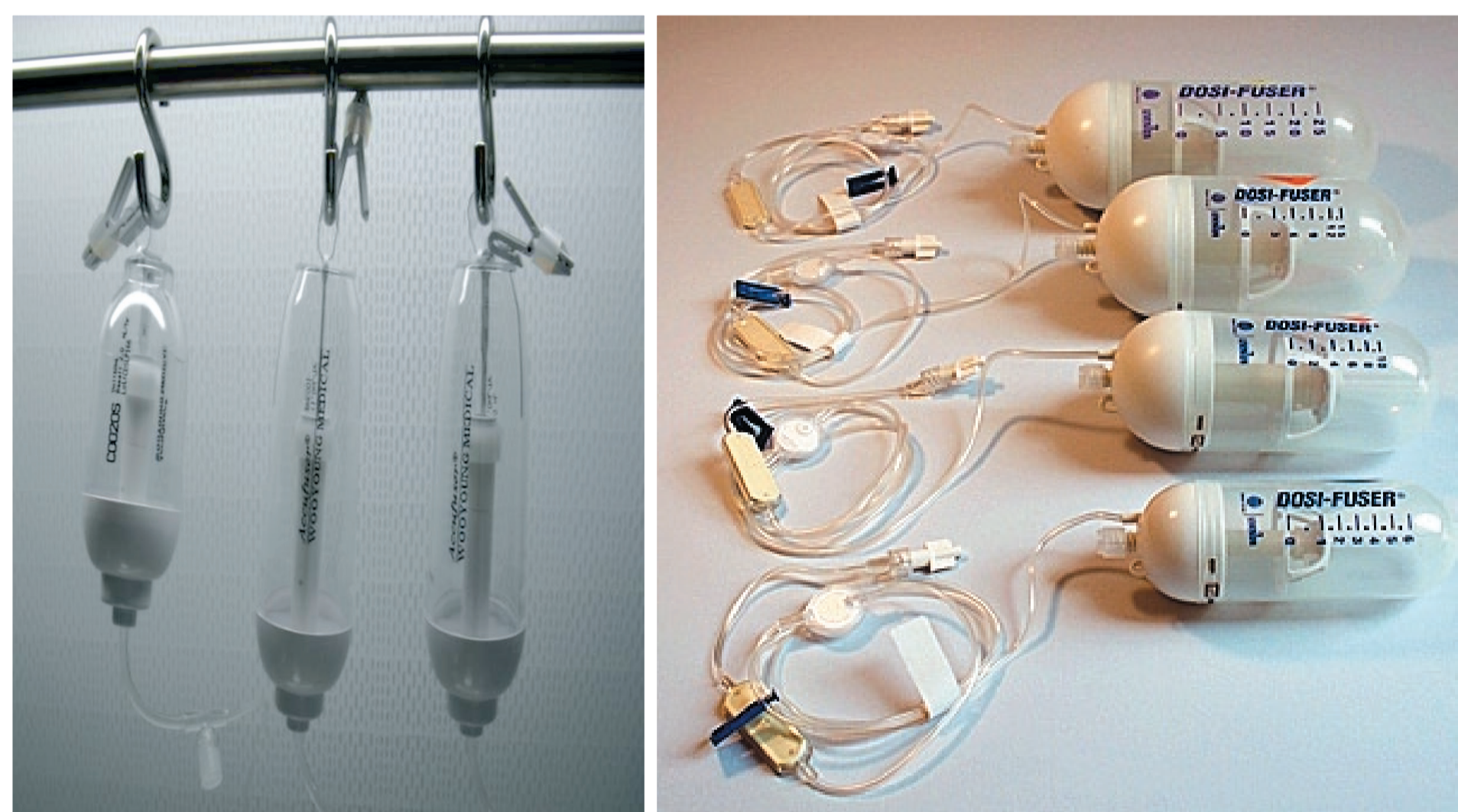


Figure 1 - Examples of infusers

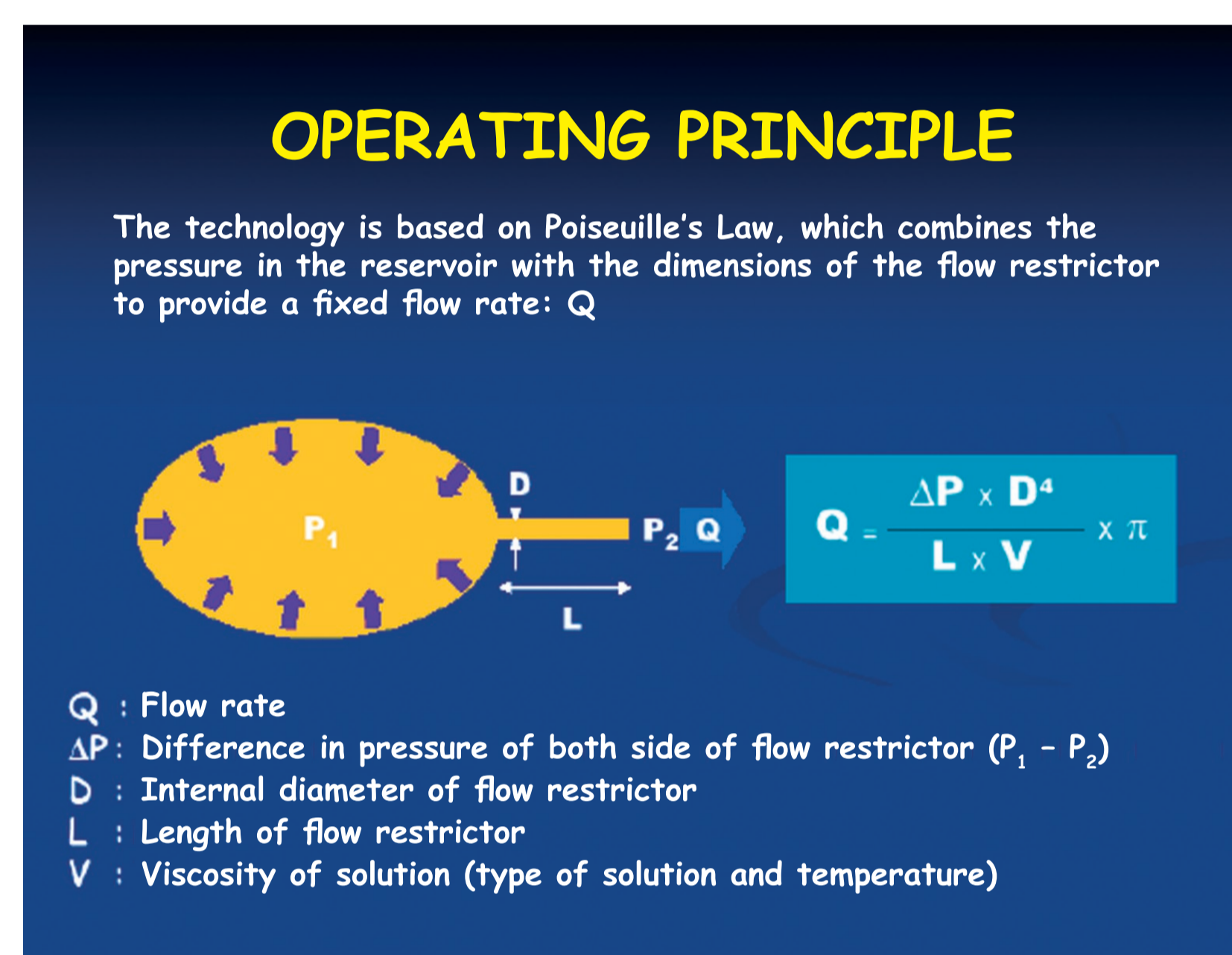


Figure 2 - Physical principle of how the infuser works

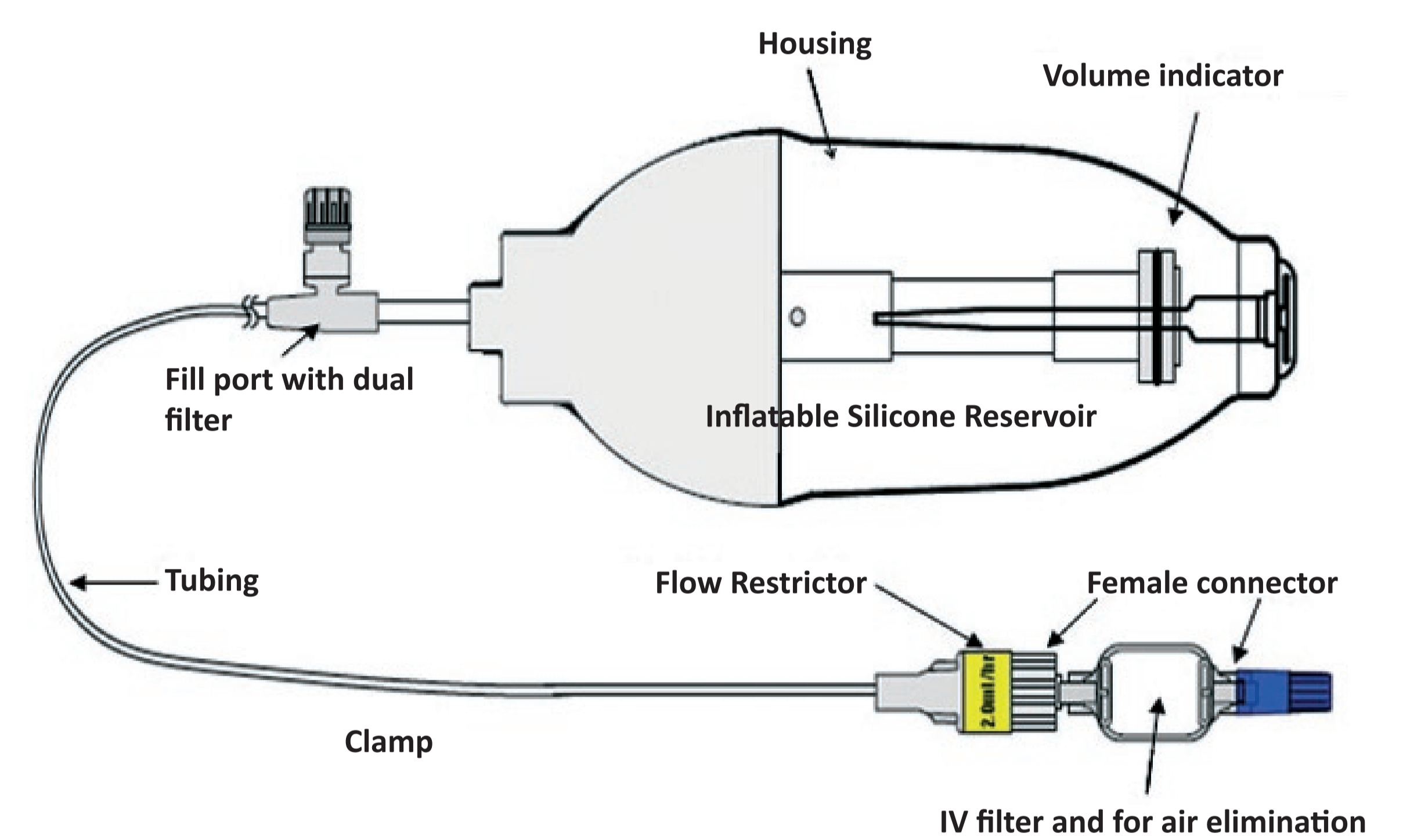


Figure 3 - Diagram of an infuser's basic parts

RESULTS

Most of the elastomeric infusion devices provide an infusion accuracy of +/-15% following the conditions established by the manufacturer.

Other variables affecting the accuracy of the infusion are:

1. Temperature. It modifies the viscosity of the mix. It is estimated that a change in one degree in temperature brings variations in the flow speed of 2-3 %.
2. Viscosity. Viscosity has an inverse effect over flow, and speed decreases when viscosity increases.
3. Concentration. Concentration in the product will have a significant impact on viscosity.
4. Atmospheric pressure. Low pressures (600 mmHG) may bring important reductions in the infusion speed.
5. Back pressure. If infusion devices are calibrated in a particular position a change in that position modifies accuracy.
6. Storage. It is important to temper the infusion device before use, to avoid variations in the viscosity of the fluid and in the texture of the elastomer membrane, etc.
7. Risk of precipitation 5- FU. Risk of precipitation has to be minimized to avoid the capillary collapse. It is important to pre-filter with a 0.45m filter before filling.

APPENDIX 2- EXAMPLE OF PATIENT INFORMATION SHEET

PATIENT INFORMATION

HOSPITAL LOGO

You are receiving 5-fluorouracil (5-FU) through an infuser as part of your chemotherapy treatment. As the internal balloon deflates, the drug will enter your body.

START OF INFUSION

At the end of the session in the day hospital, a nurse will connect the infuser to its reservoir. The nurse will ensure that the clamp (that can be used to stop infusion if necessary) is open and the drug is flowing correctly through the infusion line. The pump will work in any position as long as the clamp is open.

DURING THE INFUSION

Once the nurse confirms that the infuser is properly connected, you can be discharged from the day hospital. The infuser's balloon will become deflated and will infuse the drug into your body for approximately 2 days.

You can perform everyday activities (walking, driving, etc.) while wearing the connected infuser but avoid extreme activities until the infusion has finished.

Make sure that the clamp remains open while receiving treatment.

Keep the infuser in contact with your body to maintain a constant temperature, since changes in temperature can affect the infusion rate.

ENDING THE INFUSION

The infusion must be stopped before the balloon is completely deflated. You will be shown how this is done at the day hospital.

REMOVING THE INFUSION

ONLY the nurse should remove the infuser.

FAQS

Can I take showers?

Yes, the infuser can become wet, but must not be submerged in water. You can keep it in the plastic bag.

Where do I keep the infuser when I'm sleeping?

The infuser should be kept at the same level as the distal connector (at the end of the infusion line). For this reason, avoid placing the infuser on the floor or hanging it above head height. It may be comfortable to place the infuser under a pillow.

PROBLEMS THAT MAY OCCUR

The balloon doesn't seem to deflate

- Make sure that the clamp is open and the tubing is not kinked.
- If the infusion is extremely slow, call the day hospital.

The infuser is leaking or dripping.

- Use gloves when handling the infuser.
- Close the clamp and contact a nurse
- Place the infuser into a plastic bag if necessary and return it to the day hospital.

CONTACT NUMBER:
BUSINESS HOURS:

CONCLUSION

There is a wide variation in the conditions of use of the elastomeric infusion devices, and in its calibration. Some factors related with the use of the device affect the flow of the medication, and may also affect the safety of the patient and the effectivity of the treatment.

Implantation of an informative and educational datasheet for the patient would improve the use of the elastomeric infusion device.