

Elasto-Q Infusion Pump

Instructions For Use

Product description:

The Elasto - Q infusion pump uses the stretchable silicone reservoir to create a constant minimal drop control through a catheter (not supplied) to achieve continuous (fixed or adjustable) flow and/or for bolus applications

Intended use:

A single use device for the continuous and/or bolus administration of analgesic medicines for intraoperative, post-operative and chemotherapy medications for the management of pain

Instructions for Use:

Inspect the product. Do not use if the package is open or damaged

Using aseptic technique:

Remove the infusion pump from the sterile packaging

Verify the clamp is closed, remove the cap from the filling port and fill the balloon reservoir with the drug using a syringe (a luer lock type syringe is recommended)

During filling, make sure there is no air in the syringe, then infuse the medication (the balloon reservoir can exhaust itself)

Once the balloon reservoir is filled up with the correct liquid volume, disconnect the syringe and close the filling port with the cap

If using a PCA model: The self - control device (PCA) is the function button that the patient can use to control the additional medication when in continuous mode. By pressing the PCA button, the patient can add a limited quantity of medication in accordance with the physicians' instruction as required.

After the medication has been added, open the clamp, remove the yellow card from the self - control (PCA), and press the PCA button 1~2 times to speed up the liquid flow through the tubing. When the medicine flows from the end, close the clamp and screw the tubing end with the protective cap.

The multiple regulator device should be used only by qualified trained physician. The key should be kept secure by an appropriately assigned medical professional

To administer the medication to the patient, check there are no air bubbles in the infusion line, remove the protective cap, attach the connector to the patient's line and open the clamp

The flow rate will be a little faster (within the standard scope) during the 1 - 2 first hours of use.

That is due to the physical characteristic of the silicone material

In test conditions (temperature 23°C±2, relative humidity 50%±5 and atmospheric pressure of 86 KPa~106KPa) using purified water or distilled water for level infusion with the balloon reservoir and the end luer lock at the same level, the mean flow infusion rate accuracy is±15%.

Flow rate may be affected due to:

1) Fill Volume

Add the liquid according to the nominal volume, over or less than the fill volume will lead to an inaccurate infusion flow

2) Viscosity and/or drug concentration

The flow rate of the product is calibrated with purified water or distilled water as the medium, infusion of overly viscous liquids will result in a slower flow rate

3) Temperature

The flow rate of the product is calibrated in the temperature range of 23°C ±2. The flow rate of the product will be faster when the operating temperature is higher or conversely when lower

4) Atmospheric pressure

The flow rate of the product is calibrated under standard atmospheric pressure conditions. The flow rate of the product will be faster when atmospheric pressure is below standard or conversely when higher

5) Level infusion

The normal use of the product should be level infusion, when the balloon reservoir is higher than the end outlet will lead to a faster flow or conversely when lower

6) Storage

The product should be used as soon as possible after filling as the flow rate of the product will be slower if there is a considerable delay in use after filling

7) External pressure

Squeezing or laying on the pump increases the flow rate

Parameters

Nominal Volume (ml)	200ml, 275ml, 500ml
Nominal flow rate (ml/hr)	0-14ml
PCA volume (ml)	0.5
Refill time (mins)	15
Residual volume	<10%

Warning

- ⊗ Do not use if package is open or damaged
- ⊗ Single use only, do not resterilise, refill or reuse

Flow rate is adjustable. Medication dosage should be based on maximum flow rate.

The amount of medication over the therapeutic period and delivery time can vary up to 15%. This needs to be considered when determining medication delivery.

Regardless of the prescribed flow rate, only fill the pump with medication dosage that is appropriate to administer at the maximum flow rate.

Medications or fluids must be administered per instructions provided by the drug manufacturer. Physician is responsible for prescribing the medication based on each patient's clinical status, such as age, body weight, disease state of patient, concomitant medications, etc.

There is no alarm or alert when flow interruption occurs, therefore, life - supporting medications whose usage may cause serious injury or death due to stoppage or under - delivery are not recommended for infusion with this device

There is no indicator of pump infusion status, therefore, use caution where over - delivery of medications could result in serious injury or death. It is the responsibility of the healthcare provider to ensure patient is educated on the proper use of the system

Contraindications:

This product is not intended for infusion of blood, blood products, lipids, fat emulsions, or Total Parenteral Nutrition (TPN).

This device is not suitable for patients who are allergic to an analgesic or suffering from respiratory disease, severe disturbance of circulatory function, shock or severe pain. It should be cautiously used in its application with the elderly

This device cannot be used for intramuscular injection

Caution

Not suitable for photosensitive drugs

Consideration needs to be made if Thermoplastic Polyurethane (TPU) material is required for clinical use

Inject the medication according to the marked volume of the product

Residual volume is < 10%

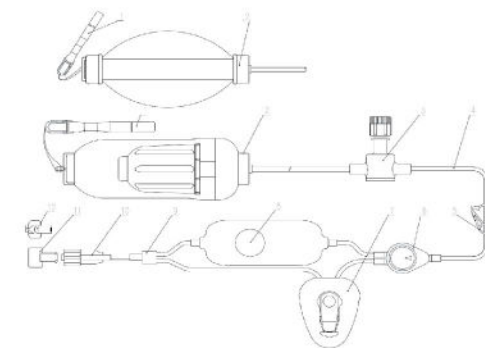
For single use only, discard after use

For PCA function, remove the yellow card on the PCA before use

Store in dry place at room temperature, protect from moisture and light

Description of device

1.Strap 2.Silicon liquid storage device 3. Single-way filling port 4.Tubing 5.Clamp 6.Vent filter 7. Self-control device (PCA) 8.Multiple regulator device 9.Transparent three way stopcock 10.Luer lock 11/12.Protective cap



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