Pharmacy Services

Elastomeric Products

Professional Guide

Baxter

1

The Infusor™ Promoting Patient Mobility

The Baxter *Infusor*, *Intermate* and *Folfusor* devices utilise Elastomeric technology to provide reliable infusion treatment while promoting patient recovery.

They also improve patients quality of life by allowing ambulatory treatment without the inconvenience of programming, power sources and erroneous alarms.

The major indications are:

- Infusional chemotherapy
- Pain management
- Antibiotic therapy (Cystic Fibrosis, Osteomyelitis, HIV)
- Chelation (thalassemia)

The administration routes that can be used are:

- IV
- Intra-arterial
- Subcutaneous
- Epidural
- Pain Management (incl.wound infusion and nerve blocks)

The *Infusor* or *Intermate* – with their lightweight disposable design and silent operation – allow patients to continue therapy in any setting. The *Infusor* and *Intermate* offers patients a medication delivery system that is comfortable, portable and adaptable to both their therapy and lifestyle needs.

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How should the devices be stored?

The *Infusor* and *Intermate* may be stored at room temperature or in the refrigerator. Storage conditions are determined by drug stability.

To store the *Infusor* or *Intermate* at ROOM TEMPERATURE choose a cool, dry place that is:

- Clean
- Away from direct sunlight
- Away from heat sources such as an oven or heater
- Where the *Infusor* or the *Intermate* won't get damaged

To store the *Infusor* or *Intermate* in THE REFRIGERATOR:

- Make sure the *Infusor* or the *Intermate* are not touching each other so air can circulate around them.
- Keep the *Infusor* or the *Intermate* in a separate compartment of the refrigerator.
- If using an *INTERMATE* device, allow the device to warm up to room temperature before use (approx 4-6 hours)

Important points to note:

- Don't expose the *Infusor* to extremes of temperature or direct sunlight.
- Patients should try not to get their catheter wet in the shower.
- Patients should keep the *Infusor* and the *Intermate* out of the reach of children.
- The *Infusor* and *Intermate* are single use only.
- The *Infusor* and *Intermate* devices must be filled in accordance with the directions for filling and priming.
- Do not overfill the devices.
- Do not fill less than 1/3rd of the capacity of the device.
- Epidural administration of drugs other than those indicated for epidural use could result in serious injury to the patient.
- The *Infusor* LV device is not designed for rapid infusion of medications.

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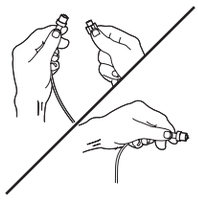
Using the Infusor™ or Intermate™

Getting ready to use the devices

1. The *Infusor* should be **removed from the refrigerator directly before use** unless otherwise instructed. The *Intermate* should be removed from the refrigerator 4-6 hours before use unless otherwise instructed.
2. **Clean a flat surface** with soap and water and dry thoroughly
3. **Assemble everything you're going to need on the clean surface.** Lay out these instructions where you can follow them, without having to touch them, as you connect your *Infusor* or *Intermate*.
4. Check the **name of the medication** on the label.
5. **Check the expiration date** on the label.
6. Check that **your name is correct** on the label.
7. **Wash your hands with hot water and soap.** Dry thoroughly.

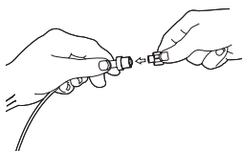
Connecting the *Infusor* or *Intermate* to the catheter

1



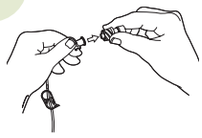
Remove the luer cap from the end of the *Infusor* or *intermate* tubing. Check to make sure that liquid has moved to the end of the tubing.

2



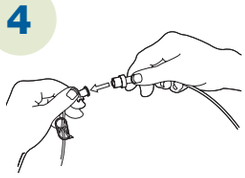
Replace the Luer Cap.

3



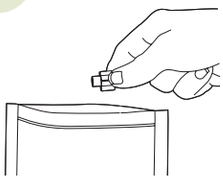
Flush the IV line as instructed. Make sure that the catheter is clamped, then remove and discard the end cap.

4



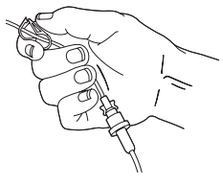
While still holding the IV line, pick up the *Infusor* tubing, **remove the Luer Cap and connect it to the catheter.**

5



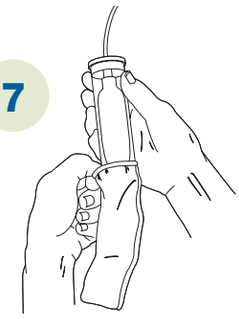
Store the Luer Cap in the bag the *Infusor* came in.

6



Unclamp the catheter so that the infusion can commence.

7

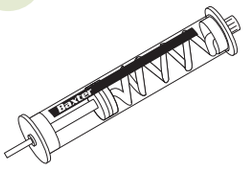


The patient should place the *Infusor* or *Intermate* in the mesh bag or belt bag provided, where the device won't fall out or get damaged.

NB - Where possible if not contra-indicated, the flow restrictor of the Infusor should be taped to the patients skin to facilitate nominal flow rate.

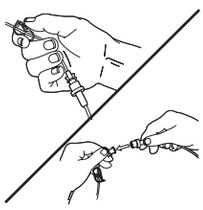
Disconnecting the *Infusor* or *Intermate*

1



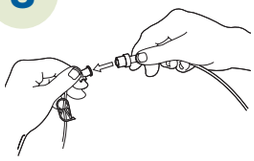
When the *Infusor* or *Intermate* is empty remove it from the catheter. If you're not sure whether it's completely empty, please refer to the section 'Checking the progress of your infusion'.

2



Close the clamp on the catheter and disconnect the Luer Connector end of the *Infusor* or *Intermate* from your catheter by gently twisting anti-clockwise.

3



Flush the catheter the way you have been instructed and attach a new sterile end cap. Place the Luer Cap you saved earlier on the end of the *Infusor* or *Intermate.* Dispose of the empty *Infusor* or *Intermate* the way you have been directed.

What to do if the **medication does not infuse**

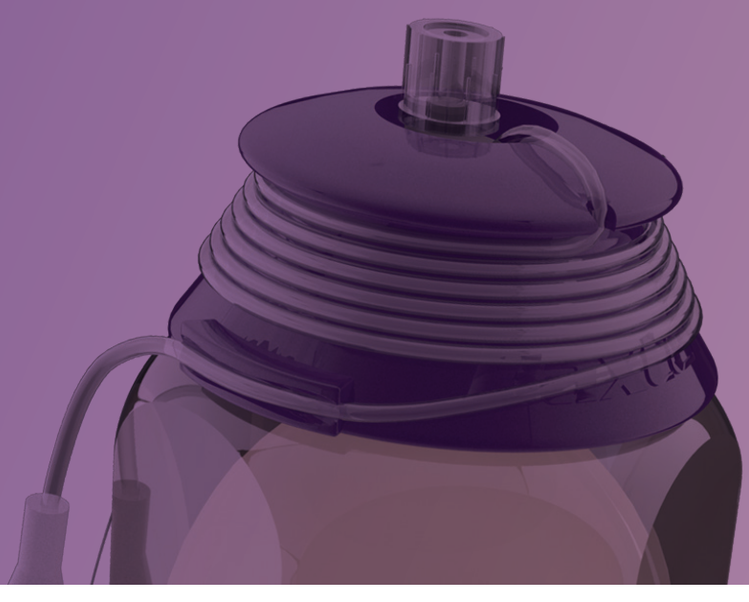
1. Remember the *Infusor* or *Intermate* flows very slowly so **make sure you have waited long enough.**
2. **Check that the IV line is unclamped** and that there are no kinks in the line.
3. If the medication is still not flowing, **clamp the catheter and disconnect the *Infusor* or *Intermate***. Replace the Luer Cap on the end of the *Infusor* or *Intermate* tubing.
4. **Make a note** of the *Infusor* or *Intermate* code number.

What to do if the ***Infusor* or *Intermate* leaks or bursts**

1. Immediately **clamp the catheter.**
2. **Disconnect the *Infusor* or *Intermate*** and replace the Luer Cap on the end of the *Infusor* or *Intermate* tubing.
3. **Attach a new *Infusor* or *Intermate***, or cap the catheter.
4. **If medication comes into contact with the patient's skin, immediately wash the area with warm, soapy water.**
5. **If your hospital or community service has provided you with a spill kit, refer to instructions in the kit for managing spills.**
6. **Make a note** of the *Infusor* or *Intermate* code number.

Do not use the device if

- The **expiration date** on the label has passed.
- The name on the **label is incorrect.**
- The **balloon has burst** or is split.
- There is **any sign of leaking** drug.
- There is a **split or break in the tubing**.
- The **Luer Cap has been removed or is missing.**
- The **Fill Port Protector Cap is missing** or has fallen off.



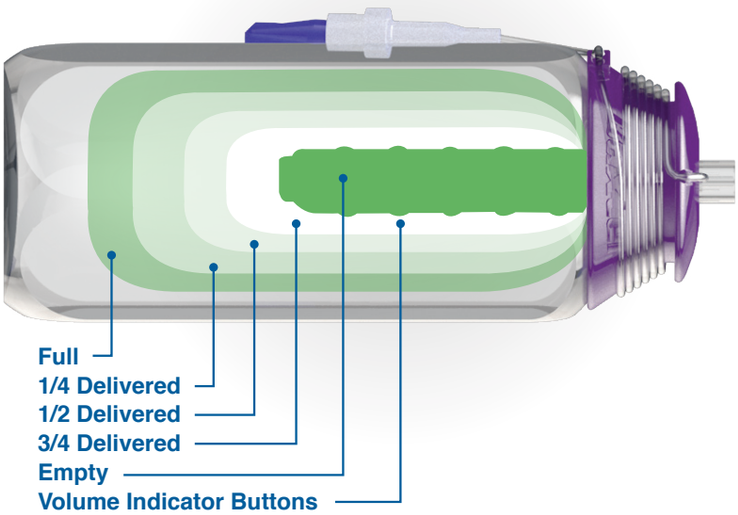
Checking the progress of the infusion

The patient may receive more than one *Infusor* or *Intermate* to deliver all their medication. Depending on the type of *Infusor* or *Intermate* that was given, it will take approximately 30 minutes to 7 days forthe *Infusor* or *Intermate* to empty.

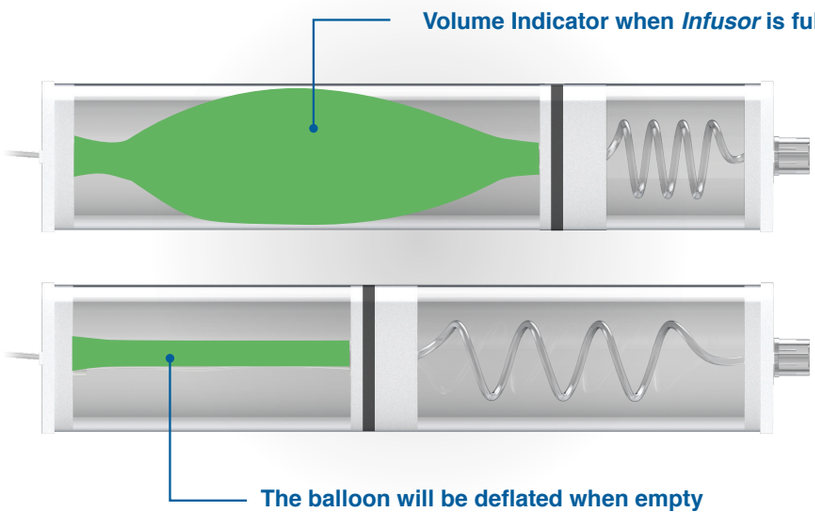
Small-Volume *Infusor*, Large-Volume *Infusor*, Small-Volume *Intermate*, Large-Volume *Intermate*

You will know when the *Intermate* or Large-Volume *Infusor* is empty as the balloon will be touching all eight empty indicator bumps on two sides ofthe *Infusor* or *Intermate*. The *Infusor* or *Intermate* works slowly so the balloon will appear to be shrinking over several hours or days.

The diagram below shows you approximately how the balloon deflates over time.

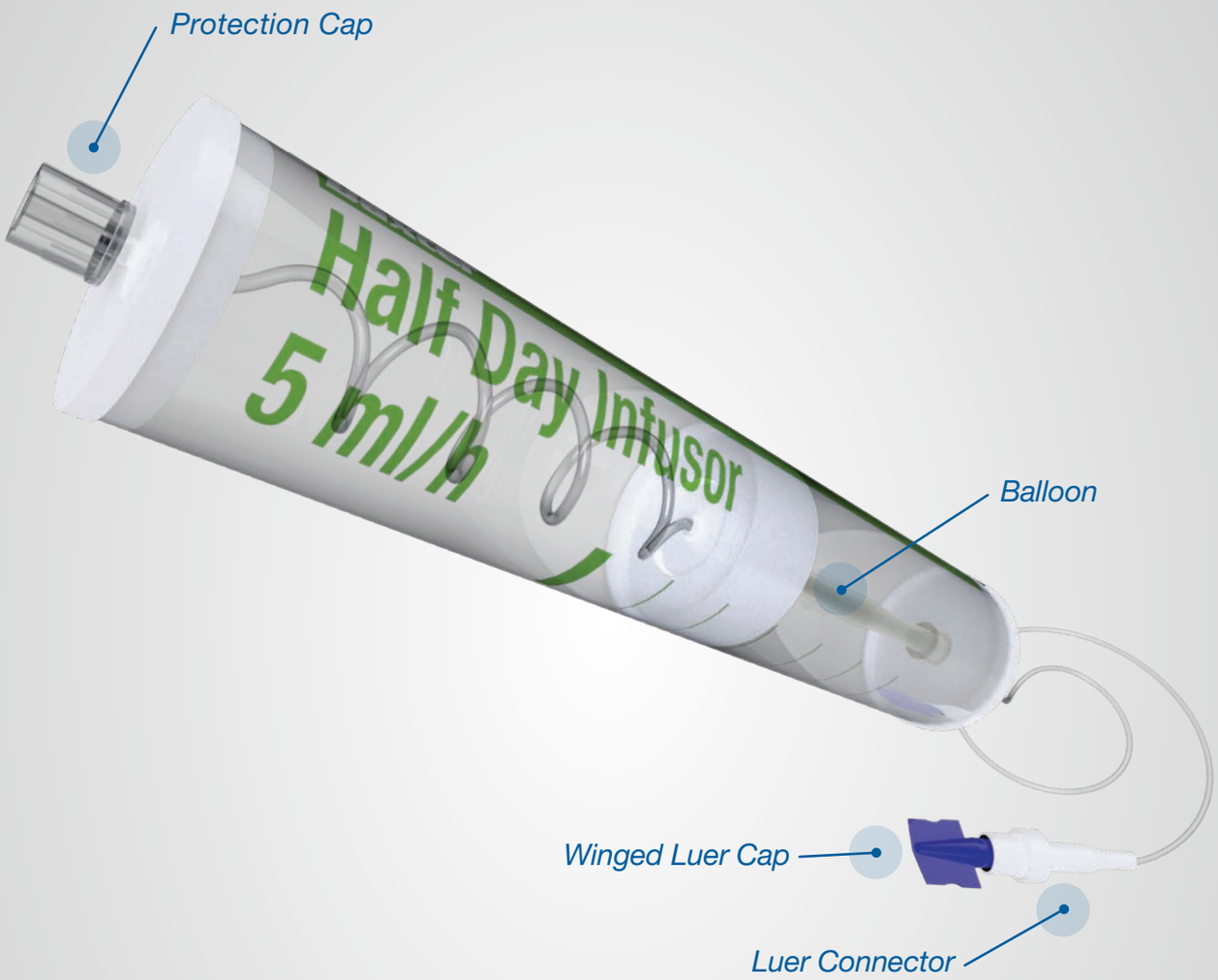


The *Infusor*



Large Volume Infusor™

Small Volume Infusor™



4 Parameters for Use

Temperature

The *Infusor* device is designed to operate at the nominal flow rate when the flow restrictor of codes 2C1073KJ, 2C1063K, and 2C1009K are at a temperature of 31.1° C (88°F). All other *Infusor* codes are designed to operate at the nominal flow rate when the flow restrictor is at a temperature of 33.3° C (92° F).

The *Intermate* device is designed to operate at the nominal flow rate at a temperature of 21.1° C (70° F).

Flow rate will decrease approximately 2.3% per 1° C (1.8° F) decrease in temperature and will increase approximately 2.3% per 1° C (1.8° F) increase in temperature.

Head height

Flow rate of the *Infusor* device is optimised when the Elastomeric Reservoir and the Distal End Luer Lock are positioned at the same height. Flow rate will decrease approximately 0.5% per 2.54 cm (1 inch) if the Elastomeric Reservoir is positioned below the Distal End Luer Lock. Flow rate will increase approximately 0.5% per 2.54 cm if the Elastomeric Reservoir is positioned above the Distal End Luer Lock.

Viscosity

The *Infusor* device is designed to operate at the nominal flow rate using 5% Dextrose (D5W) as the diluent to provide the correct fluid viscosity.

There will be an approximate 10% increase in the nominal flow rate when 0.9% Sodium Chloride (NS) is used.

The *Intermate* device is designed to operate at the nominal flow rate using 0.9% Sodium Chloride (NS) as the diluent to provide the correct fluid viscosity. There will be an approximate 10% decrease in the nominal flow rate when 5% Dextrose (D5W) is used.

Catheter size

When delivering solution through a catheter refer to the directions for use provided by the catheter manufacturer. The length, diameter, and location of the catheter can decrease flow rate. A 22 gauge (3 French) or larger diameter catheter should be used with the *Infusor* to achieve nominal flow rates.

An 18 gauge (4 French) or larger diameter catheter should be used with the *Intermate* to achieve nominal flow rates.

5

Trouble-shooting

Problem Description
High Flow

Where was the flow restrictor placed on the patient?

The *Infusor* operates at the labelled nominal rate when the *Infusor* flow restrictor is taped to the skin in the correct location (See temperature information.)

A temperature of 31.1ºC is achieved when the flow restrictor is taped to a peripheral location on the patient's skin. A temperature of 33.3°C is achieved when the *Infusor* flow restrictor is taped to a central location on the patient's skin. The *Intermate* operates at the labelled nominal rate when the flow restrictor is at room temperature (21.1°C). The *Intermate* contents must be at room temperature in order for the *Intermate* flow restrictor to be at room temperature (See temperature information.)

What was the viscosity of the solution in the device?

See viscosity information.

Was the flow within tolerance?

The *Infusor* flows within +/- 10% - 12.5% of the labelled nominal flow rate. The *Intermate* flows within +/- 15% of the labelled nominal flow rate (please refer to the table on page 13 to determine acceptable flow ranges)

Was any direct heat source (heating pads, heated water bed, heating blanket) or indirect heat source (sunlight) placed on or near the flow restrictor of the *Infusor* or the housing of the *Intermate*? Was the patient's body temperature elevated?

Direct or indirect heating of the *Infusor* flow restrictor or *Intermate* flow restrictor may cause a faster infusion than the labelled nominal flow rate (See attached temperature information.)

What volume of drug/diluent was used in the device?

Underfilling the *Infusor* device will result in a flow rate that is higher than the labelled nominal flow rate. The nominal flow rate is achieved by utilising the fill volumes listed in the product chart.

Was the flow restrictor placed at the same head height as the *Infusor*?

See the Head Height information.

Problem Description
Low Flow & No Flow

Was the flow within tolerance?

The *Infusor* flows within +/- 10% - 12.5% of the labelled nominal flow rate. The *Intermate* flows within +/- 15% of the labelled nominal flow rate (please refer to the table on page 13 to determine acceptable flow ranges)

Was the flow restrictor in contact with any cooling source?
Was the flow restrictor taped to the patient's skin?
Was the filled *Intermate* brought to room temperature prior to use?

Viscosity of the drug solution will influence flow rate. Changes in the temperature of the flow restrictor will change the viscosity of the drug solution contained inside – thereby changing the flow rate.

Cooling the *Infusor* or *Intermate* flow restrictor to a temperature below the nominal temperatures (see product information charts) will reduce the flow rate. If not contra-indicated, the *Infusor* flow restrictor should be taped to the patients skin to achieve nominal flow rate. If the flow restrictor is not taped to the patients skin, the flow restrictor may not be at the correct temperature to achieve the nominal flow rate.

The *Intermate* contents must be at room temperature to achieve the nominal flow rate.

What was the viscosity of the solution in the device?

See Viscosity information.

What volume of drug/diluent was used in the device?

Overfilling the *Infusor* device will result in a flow rate that is lower than the labelled nominal flow rate. The nominal flow rate is achieved by utilising the fill volumes listed in the product information chart.

Was the flow restrictor placed at the same head height as the *Infusor*?

See Head Height information.

Was air removed from the *Infusor* tube set and flow restrictor prior to use?
Was flow verified by visualising 2-3 drops of fluid flowing from the flow restrictor at the time of the filling and at the time of use?

Air in the *Infusor* tube set or flow restrictor may potentially result in a 'Low Flow' or 'No Flow' condition. A visual confirmation of 2 drops of fluid flowing from the flow restrictor will ensure that the flow restrictor is cleaned of all air bubbles prior to use.

Problem Description
Priming Difficulty

Were Baxter filling chart instructions followed? Was the *Infusor* filled slowly? Was the *Infusor* filled while holding the device in a vertical position?

The filling technique recommended by Baxter is the technique that has been validated in our Quality Assurance Laboratories. This technique should be used for optimal priming results. It is important to fill the *Infusor* very slowly. Remember to gently and slowly crack the Duckbill Valve and push fluid into the device until the Elastomeric balloon begins to inflate.

Was force-priming technique utilised?
Was continuous suction applied during force-priming?
Was three-way stopcock open during force priming? Was a 10mL or smaller syringe used to force prime the device?

Modifications to the recommended force priming technique may result in poor force priming results.

Problem description
Leaks

Was the fill port capped after filling? Was the fill port swabbed after filling?

Normal residual drug in the filling port can sometimes be reported as a leak. To avoid this type of complaint report, suggest that the customer wipe away residual solution with a sterile swab after filling. Also ensure that Fill Port cap is replaced after filling to avoid leakage of this residual solution.

Was the Winged Luer Cap tightened after filling the device?

The Winged Luer Cap is not tightened during the manufacturing process. The Customer must perform tightening of the cap after filling and priming are completed.

Problem description
Ruptures

Was the *Infusor* stored in the presence of sunlight or UV light?

Sunlight or UV light may damage the Elastomeric material of the *Infusor* and *Intermate* reservoirs.

6

Large Volume *Infusor*

Specifications				
Name	LV10	LV5	LV2	LV1.5
Code	2C1063KP	2C1009KP	2C1008KP	2C1087KP
Nominal Infusion duration	1 day	2 days	5 days	7 days
Nominal Flow Rate	10 mL/h	5 mL/h	2 mL/h	1.5 mL/h
Nominal Fill Volume	240 mL	240 mL	240 mL	252 mL
Nominal Temperature	31.1°	31.1°	33.3°	33.3°
Flow Rate Accuracy	+/- 10%	+/- 10%	+/- 10%	+/- 10%
Acceptable Flow Times	21.8-26.7 hrs	43.6-53.3 hrs	109.1-133.3 hrs	152.7-186.7 hrs

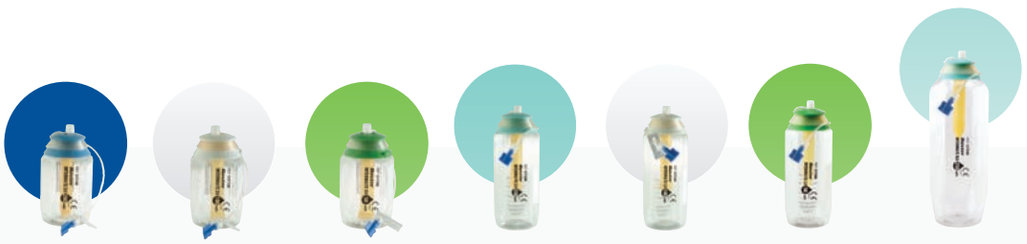
Folfusor

Specifications			
Name	SV2.5	SV0.5	SV5
Code	2C4711K	2C4700K	2C4705K
Nominal Infusion duration	2 days	7 days	1 Day
Nominal Flow Rate	2.5 mL/h	0.5 mL/h	5 mL/h
Nominal Fill Volume	120 mL	84 mL	120 mL
Nominal Temperature	33.3°	33.3°	33.3°
Flow Rate Accuracy	+/- 10%	+/- 10%	+/- 10%
Acceptable Flow Times	43.4-53.2 hrs	153.4-186.2 hrs	21.49-26.40 hrs

Small Volume *Infusor*

Specifications					
Name	Half Day	Single Day	Two Day	Multi Day	Seven Day
Code	2C1073KJP	2C1071KJP	2C1075KJP	2C1080KJP	2C1082KJ
Nominal Infusion duration	12 hours	1 days	2 days	5 days	7 days
Nominal Flow Rate	5 mL/h	2 mL/h	2 mL/h	0.5 mL/h	0.5 mL/h
Nominal Fill Volume	60 mL	48 mL	96 mL	60 mL	84 mL
Nominal Temperature	31.1°	33.3°	33.3°	33.3°	33.3°
Flow Rate Accuracy	+/- 12.5%	+/- 12.5%	+/- 12.5%	+/- 12.5%	+/- 12.5%
Acceptable Flow Times	10.7-13.7 hrs	21.3-27.4 hrs	42.7-54.9 hrs	106.7-137.1 hrs	149.3-192.0 hrs

Acceptable Flow Times
at Nominal Conditions



Intermate

Specifications							
Name	SV200	SV100	SV50	LV250	LV100	LV50	XLV250
Code	2C1714K	2C1712K	2C1710K	2C1724K	2C1722K	2C1720K	2C1754K
Nominal Infusion duration	30 mins	60 mins	120 mins	60 mins	2.5 hrs	5 hrs	120 mins
Nominal Flow Rate	200 mL/h	100 mL/h	50 mL/h	250 mL/h	100 mL/h	50 mL/h	250mL mL/hr
Nominal Fill Volume	100 mL	100 mL	100 mL	250 mL	250 mL	250 mL	500mL
Nominal Temperature	21.1°	21.1°	21.1°	21.1°	21.1°	21.1°	21.1°
Flow Rate Accuracy	+/- 15%	+/- 15%	+/- 15%	+/- 15%	+/- 15%	+/- 15%	+/- 15%
Acceptable Flow Times	26-35 mins	52-71 mins	104-141 mins	52-71 mins	2.2-2.9 hrs	4.3-5.9 hrs	1.4-2.2 hrs

Accessories

Specifications			
Name	Belt Bag 18 inch waist strap	Belt Bag Small	Mesh Bag for the *Infusor*
Code	IPB102XLX1	2C1100	BG3386WH
Pack Size	30	6	500

Infusor Applications

LV the *Infusor*	Large volume the *Infusor* used for Chemotherapy, Antibiotics and Pain Management
SV the *Infusor*	Small Volume the *Infusor* used for Chemotherpay and Pain Management
Folfusors	Small Volume the *Infusor* for Chemotherapy
The *Intermate*	Fast flowing devices for Antibiotics and IVig Infusions

7

Can concurrent Infusions be run with the Baxter *Infusor*?

Yes. Concurrent infusions may be run via a Y-Site or 3-way tap, however there is a possibility that the flow rate of the *Infusor* may decrease, particularly if the pressure of the alternate infusion device is high. It is also recommended to use an anti-reflux valve to prevent flow from one line into the other.

Is the *Infusor* Recyclable?

The *Infusor* is made from recyclable material, however disposal of the device should be in accordance with individual hospital protocol.

Can the *Infusor* be used by patients with latex allergies?

Yes, all Baxter *Infusor*, *Folfusor* and *Intermate* devices are free of natural latex.

Why is it important to place the end of the administration tubing close to the skin?

The end of the administration tubing is where the *Infusor* flow restrictor is located. This restrictor is a tiny glass tube which determines the flow rate of the *Infusor*. The flow restrictor is calibrated to work best at a temperature of 31-33°C so placement next to the skin helps to maintain this constant temperature.

Can the *Infusor* be used inside MRI machines or Hyperbaric chambers?

Yes, the *Infusor* does not contain any metal so is suitable to go through an MRI machine. The *Infusor* may also be used inside hyperbaric chambers. As long as the patient is exposed to the same changes in pressure as the *Infusor* device there is no hindrance to the infusion.

Frequently Asked Questions
Quick Reference Guide

Can extension sets be used with the Baxter *Infusor*?

When using an extension set, the flow restrictor located at the distal end of the *Infusor* administration tubing should still be taped to the skin if possible. Extension sets should be primed prior to connection to the patient. As a general guide, overall infusion time will be marginally lengthened when using an extension set.

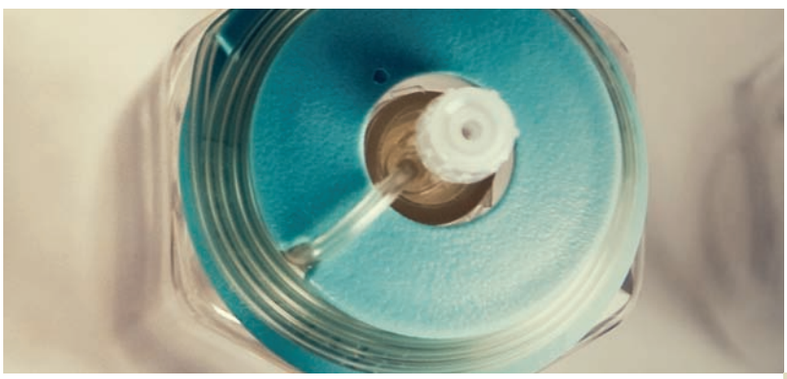
Can Baxter *Infusor* and *Intermate* devices be used during flight?

Yes, Baxter has conducted internal testing to establish the effects of cabin pressure on flow rate and solution de-gassing during flight. Results indicate that the reduced pressure environments such as those experienced during flight do not have a significant effect on solution de-gassing. Neither reduced pressure environment nor changes in gravitational acceleration have any significant effect on flow rate.

A small air bubble is noticeable in the filled *Infusor* reservoir – is this an issue?

Sometimes during the filling procedure a small number of air bubbles are introduced into the reservoir. These tiny bubbles are due mainly to the dead space in the fill port of the devices. The total volume of these bubbles is approximately 0.2 cc or 'pea-size'. These bubbles are known to 'disappear' over time; either by passing through the rubber wall (reservoir) or by dissolving into the fluid. The 'pea-size' bubble will take 24 to 29 hours to dissipate from the bladder system if the recommended filling technique is used.

Air that is inadvertently introduced during the compounding process cannot be withdrawn through the fill port. Therefore, it is important to purge air from the system (ie. syringe, diluent container, or transfer set) prior to filling the device.



For further information and support for your Baxter Elastomeric Products' please contact Baxter Customer Support on:

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