

HEALTHCARE PROFESSIONAL GUIDE

Elastomeric Products



1. **The Infusor™** Promoting Patient Mobility



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

For the purposes of this professional guide, all instructions and guidelines for the Infusor also apply to the Small Volume Infusor (Folfusor).

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

The major indications are:

- Home IV Antibiotic therapy
- Infusional chemotherapy
- Pain management
- Chelation (thalassemia)

The administration routes that can be used are:

- Intravenous (Peripheral/Midline/PICC)
- Intra-arterial
- Subcutaneous
- Epidural

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

2. 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:

- Ensure your refrigerator is clean and operating effectively. Shelf life may be adversely affected if the device is not stored between 2-8C
- Keep the *Infusor* or the *Intermate* in a separate compartment of the refrigerator.
- *Infusor* devices may be used immediately after removing them from the fridge.

Important points to note:

- Don't expose the *Infusor* to extremes of temperature or direct sunlight.
- Patients should try to not 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.
- Overfilling or underfilling your device may adversely affect its accuracy - see page 11 for more information
- Epidural administration of drugs other than those indicated for epidural use could result in serious injury to the patient.

3. 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 the *Infusor* or *Intermate*.
4. Check the **name of the medication** on the label .
5. **Check the expiration date** on the label.
6. Check that **the name is correct** on the label *(if applicable)*.
7. **Wash your hands with hot water and soap.** Dry thoroughly.

**Device is single-use only*



FILLING AND PREPARATION GUIDE

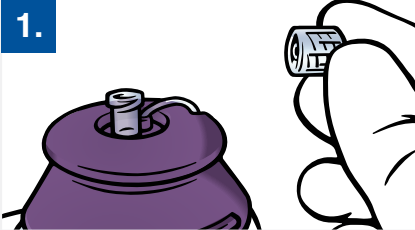
Single-Rate Slow-Flow Infusor Device™

These step-by-step instructions will guide you through the process of filling the **Single-Rate Slow-Flow Infusor** device.

The **Infusor** is filled by injecting the medication through the Fill Port using a syringe or filling system with a Luer-lock tip.

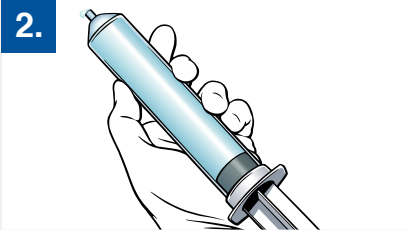
Use aseptic technique throughout. Do not use needle when filling the **Infusor** device.

1.



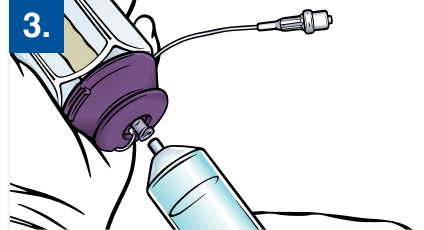
Remove paper tape from the tubing and uncoil the tube set. Remove the Sterility Protector Cap. Retain for later use.

2.



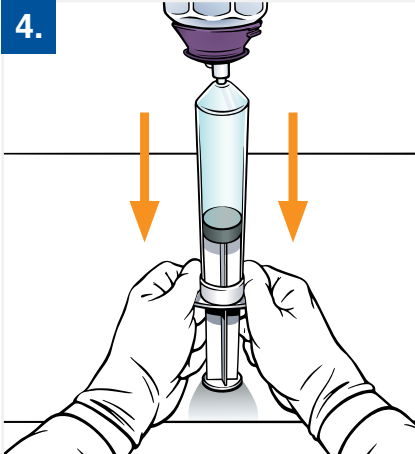
Draw up the required drug solution in a syringe.^{1,2} Prime to remove all air. Do not attach a needle to the syringe to avoid damaging the Fill Port.

3.



Insert the tip of the syringe or primed filling device into the Fill Port and turn clockwise to lock.^{1,3,4}

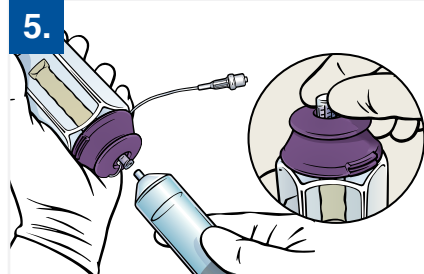
4.



Place the head of the filled syringe plunger on a work surface. Keeping the unit vertical, grasp the syringe barrel or flanges and push slowly downward on the syringe to gradually fill the Elastomeric Reservoir. Do not hold the Infusor device during filling.

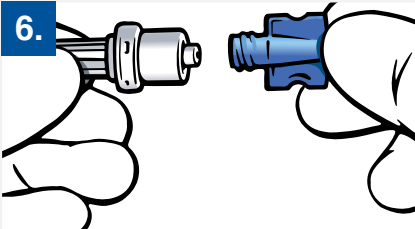
Repeat steps 2-4 to fill between the minimum and maximum fill volumes.^{5,6,8}

5.



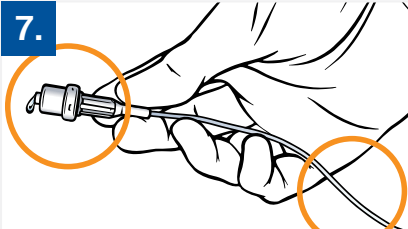
Disconnect the syringe or filling device from the Fill Port.^{4,7} Replace Sterility Protector Cap.

6.



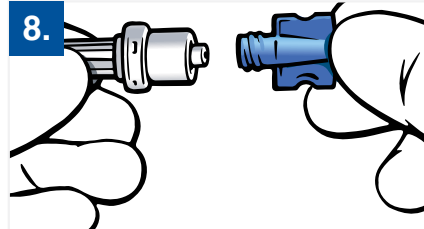
Remove the Winged Luer Cap to start system priming.

7.



Visually confirm fluid flow and that the tubing is clear of air before use. If not flowing, force prime as shown below.

8.

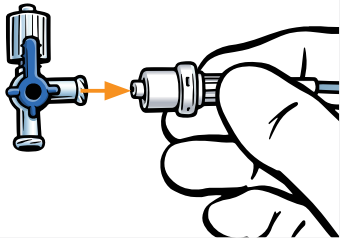


Reattach the Winged Luer Cap. Label the Infusor device in accordance with facility protocol.

¹Refer to drug manufacturer's packaging insert for drug reconstitution and storage precautions. ²Flow rate of the device is impacted by the viscosity of the solution. Reference Instructions for Use for correct diluent. ³Refer to your specific Filling Device Instructions for Use for Infusor filling instructions. ⁴Lock gently. Overtightening can damage the Fill Port. ⁵Refer to Instructions for Use for specific volume parameters per device. ⁶An under-filled device may result in an unintended faster flow rate and shorter infusion time. An over-filled device may result in a longer infusion time. It is not recommended to under-fill a device to expedite administration time. ⁷A small bubble of air in the reservoir is normal; do not attempt to remove it. ⁸Target volume = nominal volume + residual volume. Refer to the Instructions for Use for a complete list of precautions.

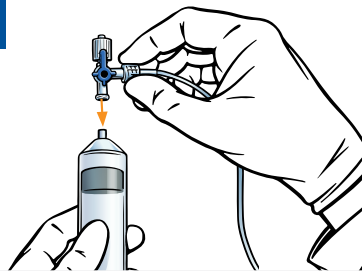
FORCE PRIME INSTRUCTIONS

1.



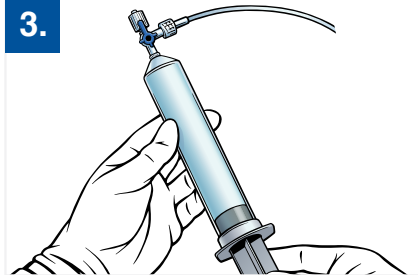
Attach a Luer adaptor or stopcock to the Infusor Distal End Luer Lock.

2.



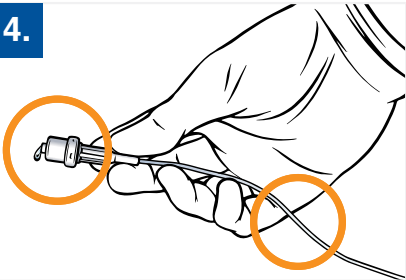
Attach a 10 mL syringe or smaller to the other side of the stopcock or Luer adaptor. Ensure the stopcock is in the "open" position.

3.



Pull back the syringe plunger to create suction. Continue to apply suction to the distal end until fluid is observed in the syringe.

4.



Visually confirm fluid flow and that the tubing is clear of air before use. Reattach the Winged Luer Cap.

CONNECTING AND DISCONNECTING GUIDE

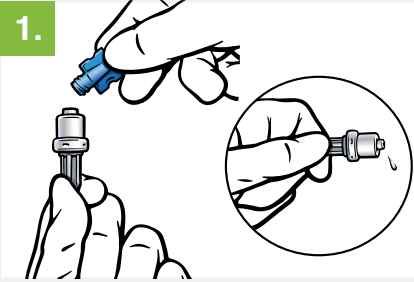
Single-Rate Slow-Flow Infusor Device™

These step-by-step instructions will guide you through the process of connecting and disconnecting your patient's **Single-Rate Slow-Flow** Infusor device to and from the catheter. It is essential that you use aseptic technique throughout.

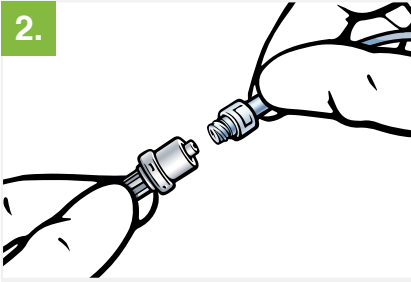
BEFORE YOU BEGIN

- Follow your facility's procedure to prepare the patient's access device

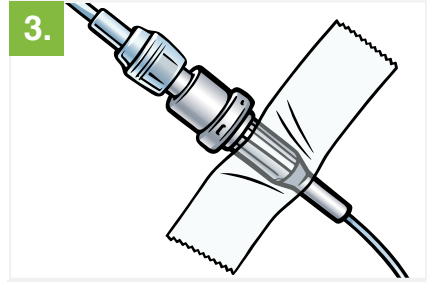
CONNECTING INSTRUCTIONS

1. 

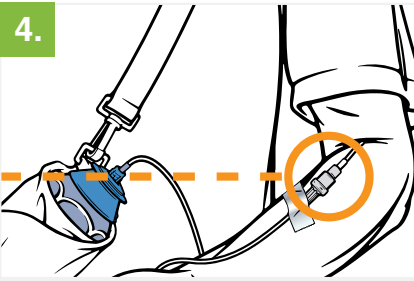
Remove the Winged Luer Cap from the Distal End Luer Lock. Confirm content is flowing.

2. 

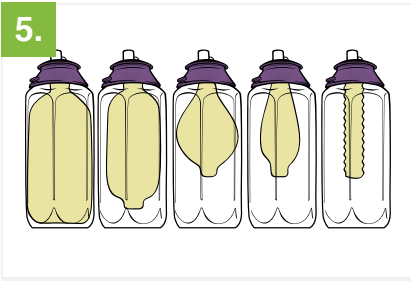
Securely connect the Distal End Luer Lock to the patient's catheter hub. If needed, unclamp the catheter to start fluid flow.

3. 

Secure/tape the Flow Restrictor directly to the skin to maintain accurate device flow rate.

4. 

Position the middle of the device at the same height as the Distal End Luer Lock.^{1,2}

5. 

Monitor infusion progress by comparing the balloon size to Progress Lines on the device.

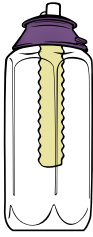
*Progress Lines may be horizontal or vertical depending on your device

¹Placing the device in a carrying pouch can assist with positioning.

²Keep the device aligned appropriately with the catheter exit site when in bed. Do not place the device on the floor. Refer to the Instructions for Use for a complete list of precautions.

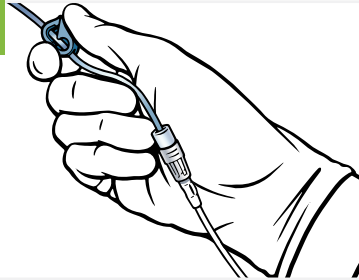
DISCONNECTING INSTRUCTIONS

1.



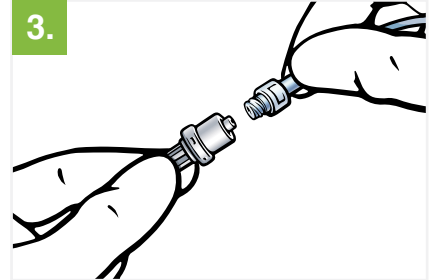
Wait until there is less than 10% volume left in the device before disconnecting.

2.



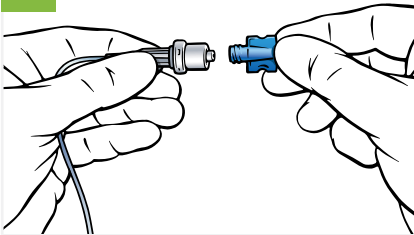
Clamp the patient's catheter (if they have one).

3.



Disconnect the Infusor device from the patient's catheter per your facility's protocol.

4.



Replace the Winged Luer Cap on the end of the Infusor device tubing. Discard unit after single use according to local regulations.

*If the winged cap is not available the device can be sealed by connecting the distal end luer lock to the fill port

CONDITIONS TO CONSIDER

- Improper use of the device can result in patient harm including medication toxicity
- Do not use if the package has been previously opened or the device appears damaged
- The device must be protected from direct sunlight at all times
- Check for solution clarity prior to administration. Do not use unless solution is clear
- Do not use an external heat source to bring the device to room temperature
- High temperatures caused by proximity to fireplaces, heaters, pets, etc., can impact administration time
- Patients must call their healthcare provider if they have a problem with the device

CORRELATION BETWEEN FLOW RATE AND EXPECTED DELIVERY TIME

Devices flowing faster than intended will have shorter delivery duration

- Warm solutions will flow quickly
- If the device is positioned too high relative to the catheter exit site, solutions will flow faster

Devices flowing slower than intended will have longer delivery duration

- Cold solutions will flow slowly
- If the device is positioned too low relative to the catheter site, solutions will flow slower
- Small size catheters (larger gage) cause solutions to flow slower.
- Refer to Instructions for Use for appropriate catheter size



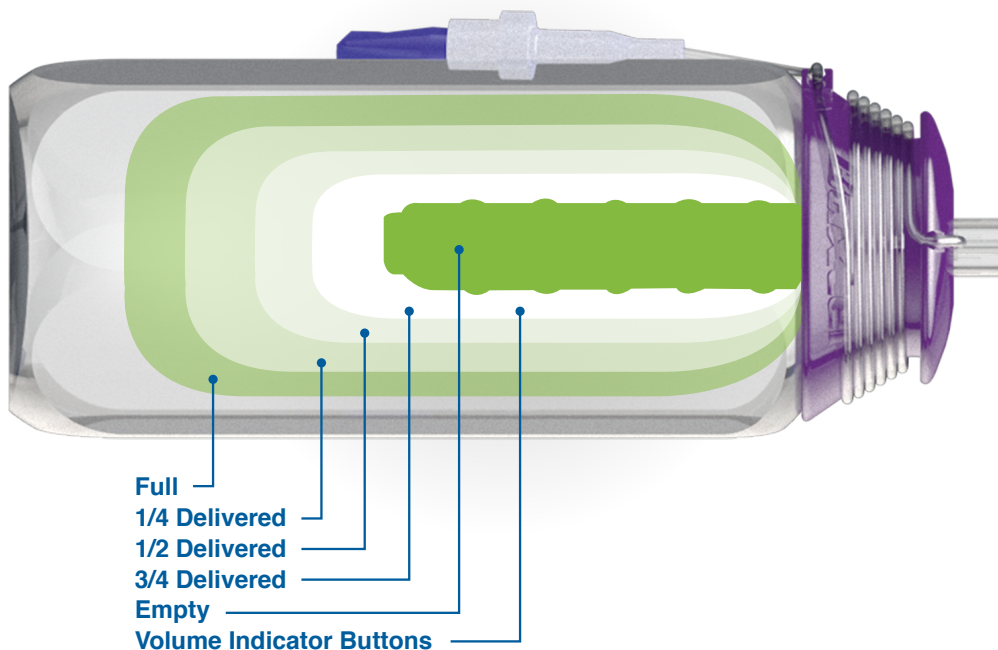
CHECKING THE PROGRESS OF THE INFUSION

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

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

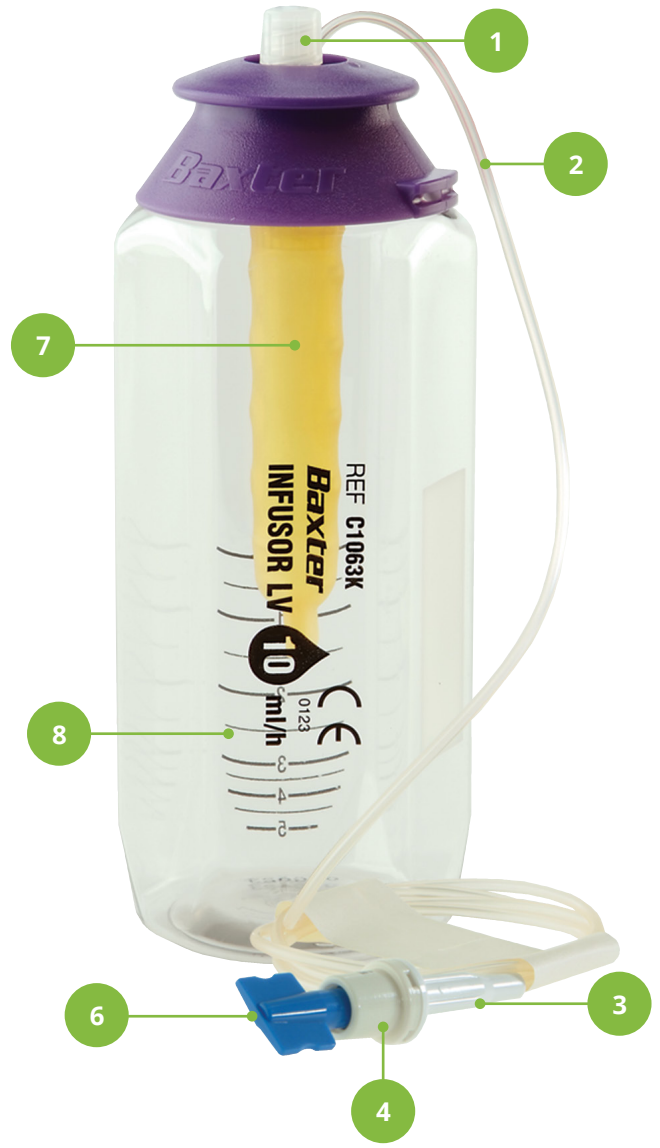
You will know when the *Intermate* or Large-Volume *Infusor* is empty as the balloon will be touching all eight empty indicator bumps on two sides of the *Infusor* or *Intermate*. The *Infusor* or *Intermate* works slowly so the balloon will appear to be shrinking over several hours or days.

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





Small Volume Infusor
(Folfusor)



Large Volume Infusor

- 1 Fill Port and Sterility Protector Cap protect the Infusor or Intermate System
- 2 Tubing carries the medication from the device into your catheter/port
- 3 Flow Restrictor (Infusor Only) controls the infusion rate of the medication (Glass)
- 4 Distal End Luer Lock attaches the Infusor or Intermate System to your catheter
- 5 Open/Close Clamp stops medication flow when pushed to the closed position; allows medication flow when in the open position. This may not be present on Infusor devices.



Small Volume
Interimate



Large Volume
Interimate

- 6 **Winged Luer Cap** protects the opening and stops the flow of medication until it is removed. The Winged Luer Cap is not present when the device is connected to your catheter
- 7 **Elastomeric Reservoir** holds the medication and pushes it through the tubing
- 8 **Infusion Progress Lines** show the progress of the infusion (lines may be horizontal or vertical on the plastic housing)
- 9 **Flow capillary (Interimate Only)** controls the infusion rate of an interimate (Stainless Steel)

4. Operating Conditions

Caution: Please note that a single or combination of the following factors may impact the flow rate:

1. Impact of Fill Volume

- The *Infusor* system is designed to operate at the nominal flow rate when it is filled with a volume ranging from the minimum fill volume to the maximum fill volume as seen on the casing of the device.
- Devices filled above the maximum or below the minimum can expect delivery variance from that stated within the instructions for use (IFU). Baxter recognizes that volumes outside the stated minimum and maximum may be necessary to account for changes in a solution's viscosity or to adjust delivery time based on the prescription required. Health Care Professionals who choose to use a fill volume outside the range specified by the minimum and maximum should expect delivery variance compared to that specified in the instructions for use (IFU).

2. Impact of Temperature

- The *Infusor* system is designed to operate at the nominal flow rate when the medication is at a temperature of 31.1°C (88°F) for 2C1009KP and 2C1063KP and 33.3°C (92°F) for 2C1087KP, 2C1008KP and 2C1156KP. To achieve the desired medication temperature, the Distal End Luer Lock/Flow Restrictor must be secured to the skin. 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 increase in temperature.

3. Impact of Viscosity of the Medication

- The *Infusor* system is designed to operate at the nominal flow rate using 5% Dextrose (D5W) as the diluent. There will be an approximate 10% increase in the nominal flow rate if 0.9% Sodium Chloride (NS) is used.

4. Impact of Head Height

- The *Infusor* system is designed to operate at the nominal flow rate when the Fill Port and the Distal End Luer Lock/Flow Restrictor are positioned at approximately the same height. Flow rate will decrease approximately 0.5% for every one inch (2.54 cm) the Fill Port is positioned below the Distal End Luer Lock/Flow Restrictor and will increase approximately 0.5% for every one inch (2.54 cm) the Fill Port is positioned above the Distal End Luer Lock/Flow Restrictor.

5. Impact of Catheter Size

- The *Infusor* system is designed to operate at the nominal flow rate when used with a 22 gauge (3 French) catheter. Use of a catheter smaller than 22 gauge (3 French) will decrease the flow rate. Always refer to the directions for use provided by the catheter manufacturer.
- Note: As a result of intra-arterial pressure, the use of the device in intra-arterial access will lead to a reduction in flow rate.

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 on page 11).

A temperature of 31.1°C 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 on page 11).

What was the viscosity of the solution in the device?

See viscosity information on page 11.

Was the flow within tolerance?

The *Infusor* flows within +/- 10% of the labelled nominal flow rate as long as the instructions for use (IFU) are observed. The *Intermate* flows within +/- 15% of the labelled nominal flow rate (please refer to the table on pages 15 and 16 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 temperature information on page 11).

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 (pages 15 and 16).

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

See the Head Height information (page 11).



PROBLEM DESCRIPTION

Low Flow & No Flow

Was the flow within tolerance?

The *Infusor* flows within +/- 10% of the labelled nominal flow rate when filled with a volume ranging from the minimum fill volume to the nominal volume plus the residual volume. The *Intermate* flows within +/- 15% of the labelled nominal flow rate (please refer to the tables on pages 15 and 16 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 on pages 15 and 16) 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 on page 11.

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 charts on pages 15 and 16.

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

See Head Height information on page 11.

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.

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* batch number.



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. Note: overtightening can cause the luer housing to crack and cause leakage.

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.



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.



Contraindications

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



6. Acceptable Flow Times at Nominal Conditions

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°
Minimum Volume	216 mL	216 mL	216 mL	227 mL
Maximum Volume	300 mL	300 mL	300 mL	300 mL
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



Small Volume Infusor (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	5mL/h
Nominal Fill Volume	120 mL	84 mL	120 mL
Nominal Temperature	33.3°	33.3°	33.3°
Minimum Volume	108 mL	76 mL	108 mL
Maximum Volume	121 mL	85 mL	121 mL
Flow Rate Accuracy	+/- 10%	+/- 10%	+/- 10%
Acceptable Flow Times	43.4-53.2 hrs	153.4-186.2 hrs	21.49-26.40 hrs

Intermate



Specifications

Name	SV200	SV100	SV50	LV250	LV100	LV50	XLV250
Code	2C1714K	2C1712K	2C1710K	2C1724K	2C2113K	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°
Minimum Volume	90 mL	90 mL	90 mL	225 mL	225 mL	225 mL	450 mL
Maximum Volume	105 mL	105 mL	105 mL	275 mL	275 mL	275 mL	550 mL
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

7. Frequently Asked Questions Quick Reference Guide



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 clear plastic casing 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.

What is the material of the balloon made from?

Polyisoprene.

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 and MRI Machine or Hyperbaric chamber?

The *Infusor* does not contain any metal so is suitable to go through an MRI machine. The *Intermate* is **NOT SAFE** for the MRI due to the stainless steel flow restrictor. The *Infusor* and the *Intermate* may also be used inside hyperbaric chambers. As long as the patient is exposed to the same changes in pressure as the *Infusor* or *Intermate* device there is no hindrance to the infusion.

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.

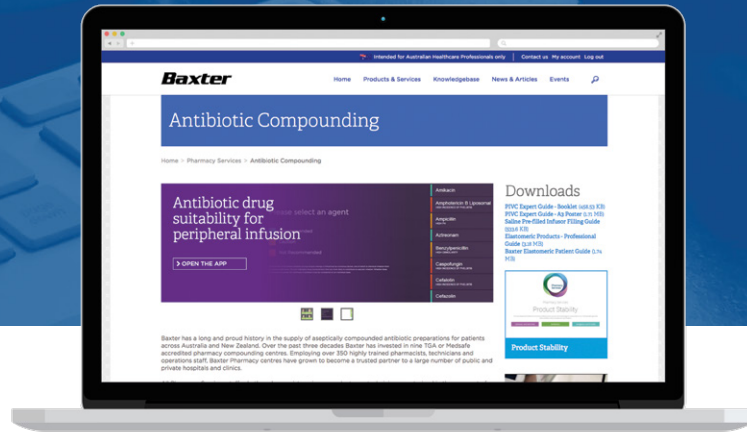
Assessing flow progression – 'Graduation lines' on the Infusor casing

The graduation lines are used to indicate general Infusor flow progression only - the lines are not directly related to a percentage of volume delivered.

The recommended way to assess the flow progression is by weighing the Infusor device over time to determine how much solution has been delivered.

Please be aware that some Infusors may deliver as little as 0.5 mL/H so ensure that enough time has passed between weighing points to determine flow progression.

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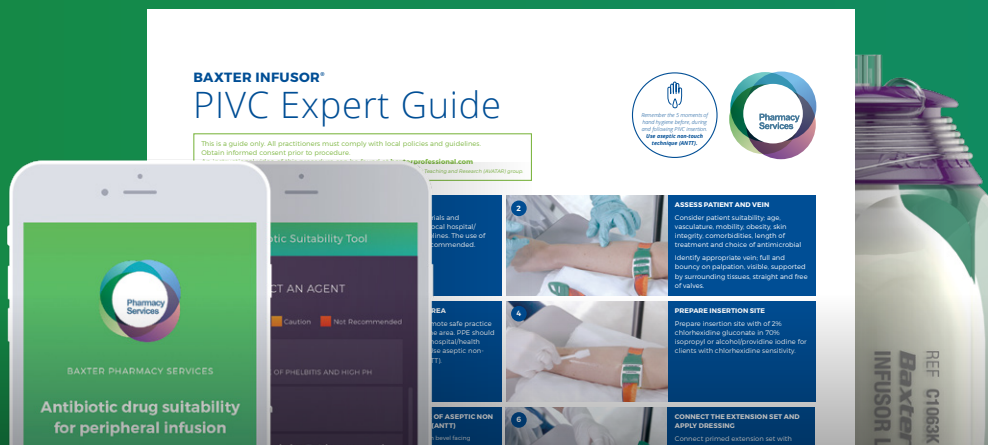
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