HOMEPUMP*

Ambulatory Infusion System

HALYARD

HOMEPUMP C-SERIES* SYSTEM
HOMEPUMP ECLIPSE* SYSTEM

CLINICAL INFORMATION

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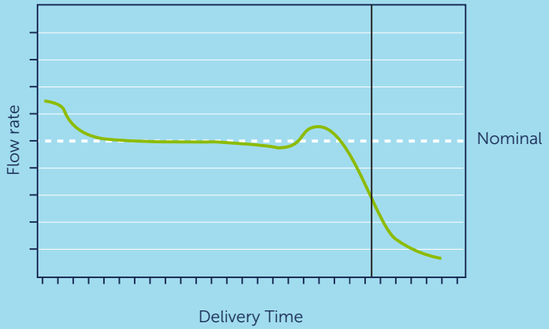
WHAT IS THE HOMEPUMP* AMBULATORY INFUSION SYSTEM?

The Homepump* System is a disposable infusion pump that is filled with medication. It operates without gravity or a power supply, making it completely portable, compact and lightweight. The Homepump* System is suitable for a variety of different medications.

HOW DOES IT WORK?

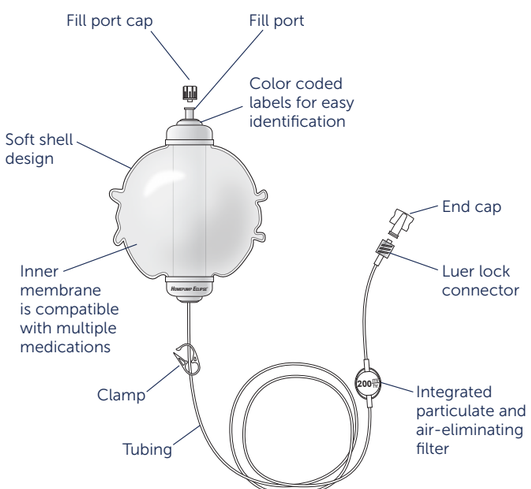
The Homepump* System consists of a balloon type, elastomeric membrane which holds the medication. The rate is controlled by restrictive tubing (Homepump Eclipse* System) or by a flow control restrictor at the end of the tubing (Homepump C-Series* System). The balloon provides the pressure to automatically infuse the medication at a preset flow rate. The rate delivers within ±15% of the labeled flow rate when used according to manufacturer's recommendations.

TYPICAL FLOW RATE

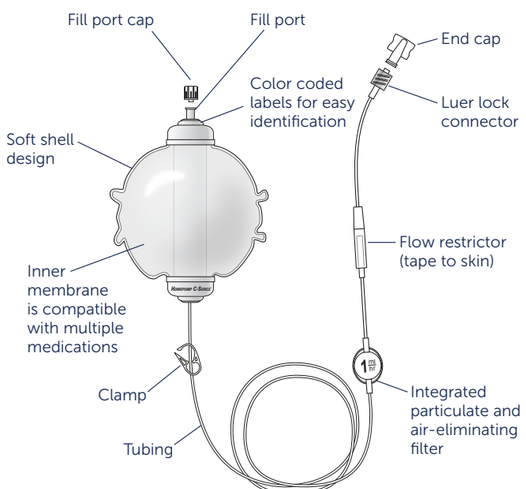


Your patient's therapy will determine whether to use a Homepump Eclipse* System or Homepump C-Series* System:

HOMEPUMP ECLIPSE* SYSTEM is used primarily for short-term infusions such as antibiotics. Depending on the size of the pump, infusions will last from 15 minutes to 5 hours.



HOMEPUMP C-SERIES* SYSTEM is used to deliver therapies, such as chemotherapy, which may infuse over 1 to 12 days.



PREPARING THE HOMEPUMP* AMBULATORY INFUSION SYSTEM

WHICH HOMEPUMP* SYSTEM IS RIGHT FOR MY PATIENT?

The Homepump* System is available in a wide variety of volumes and flow rates. The breadth of offerings provides dosing flexibility to satisfy the prescribed infusion duration. Please review the Tables on pages 4 through 7 to determine the Homepump* System that is best suited for your patient's required therapy.

DRUG STABILITY

Stability testing on a wide range of medications in the Homepump* System has been conducted by independent laboratories. The stability data relates to chemical stability of the drugs tested, not to sterility. The pharmacist dispensing the drug is responsible for ensuring proper preparation using validated aseptic techniques to prevent microbiological contamination. For practice and quality standards, refer to USP 797 Pharmaceutical Compounding - Sterile Preparations.

To obtain the most up to date drug stability information, contact your sales representative or Halyard at 1.800.448.3569 (English only) or 1.949.923.2400.

FILL VOLUMES AND DELIVERY TIMES

Use the chart on the following page to determine the appropriate fill volume per system model to achieve the desired delivery time. Information is also provided on retained volume for each system model.

⚠ **CAUTION:** The delivery times are approximate.

- Filling the pump more than the nominal fill volume decreases flow rate
- Filling the pump less than nominal fill volume increases flow rate
- Do not fill the pump less than the minimal or more than the maximum fill volume specified on the chart.

NOTE:

- It is suggested to fill the Homepump* System with diluent before adding the drug. Do not add undiluted drug first.
- The Homepump* System nominal flow rates are based on the use of normal saline as the diluent. Addition of any drug or use of another diluent may change viscosity and result in increased or decreased flow rate.
- Use of 5% dextrose will result in 10% longer delivery time.

HOMEPUMP ECLIPSE* SYSTEM

FILL VOLUMES

	E050500	E100500	E101000	E10200	E251750	E252500	E401000	E402000	E502500
Model	**50ml x 50ml/hr**	**100ml x 50ml/hr**	**100ml x 100ml/hr**	**100ml x 200ml/hr**	**250ml x 175ml/hr**	**250ml x 250ml/hr**	**400ml x 100ml/hr**	**400ml x 200ml/hr**	**500ml x 250ml/hr**
Nominal Fill Volume (ml)	50	100	100	100	250	250	400	400	500
Nominal Flow Rate (ml/hr)	50	50	100	200	175	250	100	200	250
Maximum Fill Volume (ml)	65	125	125	125	335	335	500	550	550
Retained Volume (ml)	≤ 3	≤ 3	≤ 3	≤ 3	≤ 8	≤ 8	≤ 10	≤ 10	≤ 10
Time to reach room temperature									
Refrigerator to room temp (hr)	7	8	8	8	12	12	15	15	18
Freezer to room temp (hr)	12	16	16	16	25	25	29	29	30

HOMEPUMP ECLIPSE* SYSTEM

DELIVERY TIMES FOR PARTIAL OR OVERFILL VOLUME

	E050500	E100500	E101000	E10200	E251750	E252500	E401000	E402000	E502500
Model	**50ml x 50ml/hr**	**100ml x 50ml/hr**	**100ml x 100ml/hr**	**100ml x 200ml/hr**	**250ml x 175ml/hr**	**250ml x 250ml/hr**	**400ml x 100ml/hr**	**400ml x 200ml/hr**	**500ml x 250ml/hr**
Approx. Delivery Time	**Fill Volume (ml)**								
00:15 h				60					
00:30 h	28		65	100					
00:40 h				125					
00:45 h								200	
01:00 h	50	60	100		200	250		250	300
01:15 h	65		125						
01:20 h					250	335		300	
01:30 h		80							400
01:35 h							200		
01:40 h								350	
01:45 h					300				
02:00 h		100			335		250	400	500
02:15 h								450	550
02:30 h		120							
02:35 h							300		
02:40 h		125						500	
03:00 h							350		
04:00 h							400		
04:45 h							450		
05:15 h							500		

CAUTION:

The delivery times for partial or overfill volume are approximate values.

1. Filling the pump more than nominal volume results in a slower flow rate.
2. Filling the pump less than nominal volume results in faster flow rate.
3. Do not fill the pump less than the minimal or more than the maximum fill volume specified on the chart.

To find partial or overfill volume for a particular model, look for desired delivery time in far left column then slide across to the column with model number to find fill volume.

Read product Instructions for Use for full instructions on using the Homepump* System.

To find appropriate model for desired infusion time, find time in far left column then slide across to find volume and to the top for possible model numbers. The most appropriate model will have a fill volume nearest to its nominal value.

HOMEPUMP C-SERIES* SYSTEM

FILL VOLUMES

	C060020	C100005	C100020	C125050	C270010	C270020	C270050	C270100	C300060
Model	**60ml x 2ml/hr**	**100ml x 0.5ml/hr**	**100ml x 2ml/hr**	**125ml x 5ml/hr**	**270ml x 1ml/hr**	**270ml x 2ml/hr**	**270ml x 5ml/hr**	**270ml x 10ml/hr**	**300ml x 6ml/hr**
Nominal Fill Volume (ml)	60	100	100	125	270	270	270	270	300
Nominal Flow Rate (ml/hr)	2	0.5	2	5	1	2	5	10	6
Maximum Fill Volume (ml)	65	125	125	125	335	335	335	335	335
Retained Volume (ml)	≤ 3	≤ 4	≤ 4	≤ 4	≤ 10	≤ 10	≤ 10	≤10	≤ 15
Time to reach room temperature									
Refrigerator to room temp (hr)	7	8	8	8	12	12	12	12	12
Freezer to room temp (hr)	12	16	16	16	25	25	25	25	25

HOMEPUMP C-SERIES* SYSTEM

DELIVERY TIMES FOR PARTIAL OR OVERFILL VOLUME

		C060020	C100005	C100020	C125050	C270010	C270020	C270050	C270100	C300060
Model		**60ml x 2ml/hr**	**100ml x 0.5ml/hr**	**100ml x 2ml/hr**	**125ml x 5ml/hr**	**270ml x 1ml/hr**	**270ml x 2ml/hr**	**270ml x 5ml/hr**	**270ml x 10ml/hr**	**300ml x 6ml/hr**
Approx. Delivery Time		**Fill Volume (ml)**								
12 hr		27			72				142	
18 hr		40			101				202	
22 hr		47		50	113				236	
24 hr	1 d	51		56	122			146	246	184
30 hr		60								
38 hr										257
44 hr								234		
46 hr				95				241		
48 hr	2 d			99				249		298
60 hr				114				289		335
72 hr	3 d						185	324		
96 hr	4 d						201			
120 hr	5 d		71			143	243			
135 hr	5.5 d						270			
	6 d		77			170	277			
	7 d		87			189	309			
	8 d		98			210				
	9 d		101			236				
	10 d		112			249				
	11 d		121			268				
	12 d					279				

CAUTION:

The delivery times for partial or overfill volume are approximate values.

1. Filling the pump more than nominal volume results in a slower flow rate.
2. Filling the pump less than nominal volume results in faster flow rate.
3. Do not fill the pump less than the minimal or more than the maximum fill volume specified on the chart.

To find appropriate model for desired infusion time, find time in far left column then slide across to find volume and to the top for possible model numbers. The most appropriate model will have a fill volume nearest to its nominal value.

To find partial or overfill volume for a particular model, look for desired delivery time in far left column then slide across to the column with model number to find fill volume.

Read product Instructions for Use for full instructions on using the Homepump* System.

FILLING INSTRUCTIONS

Use Aseptic Technique

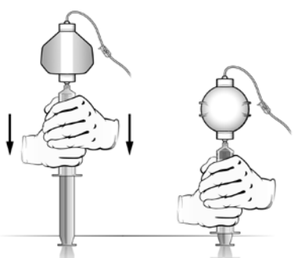
1. Remove the cap from the fill port and retain for later use.
2. The Homepump* System can be filled with a syringe or similar device. Remove all air from the filling device and attach securely to the fill port.
3. Attach the filled syringe to the fill port and invert pump as shown. Firmly grasp the syringe with both hands and push down on the plunger continuously until the volume is dispensed. Do not push down on the pump while filling, as the syringe tip may break. Repeat as necessary to reach desired fill volume.
4. Close the clamp on the tubing. Fill the Homepump* System with no more than the recommended maximum fill volume.
5. Remove filling device from the fill port.
6. Securely replace fill port cap. Ensure that the distal end cap on the tubing is tight.
7. Label with appropriate pharmaceutical and patient information.

PRIMING THE ADMINISTRATION TUBING

Use Aseptic Technique

1. Remove the cap from the distal end of the tubing.
2. Open tubing clamp. Fluid will begin to flow, filling the tubing set. When all air has been expelled from the tubing set, close the tubing clamp and replace end cap.

FILLING/PRIMING WITH DRUGS PRONE TO PRECIPITATION



Some drugs, fluorouracil (5-FU) for example, can precipitate causing medication crystallization within the pump tubing, filter or flow restrictor. Drug crystallization could result in an occlusion causing a partial or no-flow condition. To minimize the incidence of precipitation, follow the manufacturer's recommendation for storage and administration.

In order to decrease the risk of precipitation within the pump tubing, the Homepump* System can also be pre-filled and primed with a small amount of normal saline so that the drug solution is not in the pump tubing until the infusion is started. This technique can be used for any drug prone to precipitation.

1. Close the clamp on the pump.
2. Fill the pump with 10 ml of normal saline.
3. Open the clamp, remove distal luer cap, and allow the pump to prime until a drop is observed at the distal end of the set.
4. Close the clamp and replace distal luer cap.
5. Fill pump with drug and diluent needed per pharmacy protocol.
6. Do not open the clamp until ready to attach to patient.

NOTE: Fluorouracil may precipitate due to exposure to cold temperatures:

- Ensure pumps containing 5-FU are protected from cold temperatures during transport.
- Instruct patient not to refrigerate pumps with 5-FU or expose pumps to cold temperatures during infusion.
- Refer to recommendation for more information.

STORAGE

The medication within the Homepump* System will determine the pump's storage requirements. Ensure that the Homepump* System is brought to room temperature before infusing.

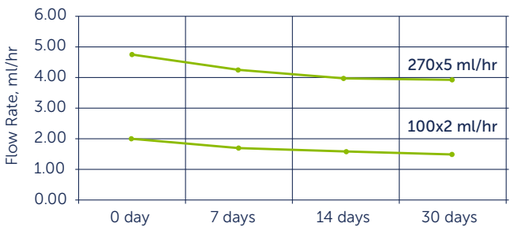
Nominal fill volume	50 – 65 mls	100 – 125 mls	270 – 300 mls
Refrigerator to room temp	7 hours	8 hours	12 hours
Freezer to room temp	12 hours	16 hours	25 hours

For additional fill volumes, see chart on pages 6 and 8.

- **Homepump Eclipse* System** Wait 4 hours after filling to start the infusion. Using the Homepump Eclipse* System immediately after filling may increase the flow rate.
- **Homepump C-Series* System** can be started immediately after filling.
  - The Homepump C-Series* System can be pre-filled and stored prior to administration. When a filled pump is stored beyond 8 hours before usage, the pressure in the reservoir will decrease due to stretch of the elastomeric membranes. This may result in a reduction in flow rate below the nominal rate.

Testing was conducted to estimate the impact of pre-filling and storing of the pumps on flow rate. The following graph shows the results when pumps were stored at room temperature.

FLOW PERFORMANCE VS. STORAGE TIME



This information reflects changes to function of the pump only. Microbial risks related to prolonged storage must be evaluated and validated by each pharmacy following guidelines from USP. Please refer to drug stability tables for appropriate duration and temperature of storage.

STARTING THE INFUSION

Use Aseptic Technique

1. Allow the Homepump* System to reach room temperature before using.
2. Verify that the clamp on the tubing is closed.
3. Cleanse injection site of patient's access device.
4. Attach the Homepump* System tubing to the access device. Begin infusion by opening the clamp; fluid delivery will start immediately. If tubing is kinked, roll kinked portion of the tubing between fingers to restore shape of tubing and promote fluid flow.

Homepump Eclipse* System	Homepump C-Series* System
The pump tubing should be worn outside the patient's clothing.	Ensure the flow restrictor is taped to the patient's skin to maintain the appropriate temperature for accurate medication delivery. Patient should wear the pump tubing inside his/her clothing.

- Catheter Size: When administering through a central or peripheral catheter, follow instructions provided by the catheter manufacturer. Peripherally inserted central catheter (PICC) lines smaller than 20 gauge x 56 cm (or other restrictive devices) will decrease flow rate.

DURING THE INFUSION

- Patient must be educated on proper use of product by healthcare provider.
- Do not use while bathing or swimming. Patient may shower if pump and access site are protected from water.
- Do not microwave or submerge in water.

During use, the pump may be placed in a carrying case, patient's pocket, or on a table/bed next to the patient. Carrying cases and clips are available to purchase from Halyard.

Instruct patients how to correctly carry the pump:

Homepump Eclipse* System	Homepump C-Series* System
Keep the pump close to the same level of the patient's access device.	Keep the pump below the patient's access device.

HOMEPUMP ECLIPSE* SYSTEM

- Depending on the size of the pump, a change in the appearance and size of the pump should be evident fairly quickly (less than 30 minutes)

2ml/hr Homepump C-Series* System after approximately 24 hours

HOMEPUMP C-SERIES* SYSTEM

- Due to the slow flow rate it may take over 24 hours to see a change in the look and size of the pump.
- Do not expect to see a change in the Homepump C-Series* System every hour.

Empty pump

- In time the outside bag will start to wrinkle and the pump will gradually become smaller.

END OF INFUSION

Infusion is complete when the elastomeric membrane is no longer expanded. Close clamp, disconnect and dispose of the Homepump* System per your institution's protocol.

⚠ CAUTIONS

- The Homepump* System is single use only. Do not reuse, re-sterilize or refill.
- The Homepump* System is sterile and nonpyrogenic. Do not use if sterile pouch has been opened, damaged, or if either protector cap is not in place.
- Do not exceed the maximum labeled fill volume of the pump.
- The Homepump* System is not intended for the delivery of blood, blood products, lipids, fat emulsions or TPN.

FREQUENTLY ASKED QUESTIONS

Are there any medications that cannot be given in the Homepump* System?	The Homepump* System is not indicated for blood or blood products, total parenteral nutrition (TPN) lipids or fat emulsions. Certain solutions may be incompatible with the PVC used in the administration set. Consult drug package insert and other available sources of information for a more thorough understanding of possible incompatibilities.
What is the filter size?	The Homepump* products include an inline 1.2 micron particulate and 0.02 micron air eliminating filter.
Is there any way to remove an air bubble from inside the Homepump* device?	It is not uncommon to have a small air bubble in the Homepump* device after filling. The air should be eliminated by the in line air eliminating filter.
What is the material in the elastomeric membranes?	The outer layer of the pumping chamber is composed of natural rubber latex. The inner membrane, which comes in contact with the drug, is a synthetic thermoplastic elastomer. This material is chemically inert, highly drug compatible and USP Class VI tested.
Can the Homepump* System be used on patients with latex sensitivity?	There is no latex in the fluid pathway and the PVC bag that covers the membranes eliminates the risk of contact dermatitis. Testing has been conducted on the latex layer of the Homepump* System to determine whether any latex proteins were extracted during the infusion. Based on current test methods available today, no latex proteins were detected during normal infusion. For more information, refer to the Latex Sensitivity Technical Bulletin.
Can a patient have an MRI while connected to a Homepump C-Series* system?	Yes. The Homepump* System does not contain any metallic or electronic parts. Homepump* products, excluding the E-clip accessory and carrying case, are deemed MR safe up to a 3-Tesla magnetic field. **If used, the E-clip and carrying case should be removed from the pump prior to MR testing.** Refer to Technical Bulletin on MRI Compatibility for more information.

TROUBLESHOOTING ISSUE RESOLUTION

The infusion is running too slowly	• Ensure that the Homepump* System and the drug within have reached room temperature after refrigerator or freezer storage. Allow at least 7 hours to reach room temperature if the device has been stored in the refrigerator and 12 hours if it has been stored in the freezer. Refer to Storage Information on page 9. • Verify that the fill volume is within the parameters for the device that is being used. Overfilling the Homepump* System will cause it to flow slower than the labeled flow rate. • Remember that the drug's viscosity can affect the flow rate when using a Homepump* System. These pumps are calibrated using normal saline, so any drug or diluent more viscous than normal saline can cause a slower than expected flow rate.
The pump is not infusing at all	• Ensure the clamp on the Homepump* System tubing is open. Also ensure any clamp on the patient's catheter is open. • Check for kinks in the Homepump* System tubing. Massage any kinks out of the tubing with your fingers. • Check to make sure the filter is not covered.
The infusion is running too fast.	• The Homepump Eclipse* System is designed to operate at room temperature (20°C/68°F). If the pump or tubing is warmer than room temperature, it may flow faster than its labeled rate. • The Homepump C-Series* System is designed to operate at skin temperature (31°C/88°F). If the pump or tubing is warmer than room temperature, it may flow faster than its labeled rate. • Verify that the fill volume is within the parameters for the device that is being used. Underfilling the Homepump* System will cause it to flow faster than the labeled rate.

There are inherent risks in all medical devices. Please refer to the product labeling for Indications, **Cautions, Warnings and Contraindications**. Failure to follow the product labeling could directly impact patient safety. Physician is responsible for prescribing and administering medications per instructions provided by the drug manufacturer. Refer to **www.halyardhealth.com** for product safety Technical Bulletins.

24-Hour Product Support Hotline (US only) 1-800-444-2728

HALYARD

For more information in the US visit
halyardhealth.com

1-800-448-3569
1-844-HALYARD (1-844-425-9273)

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