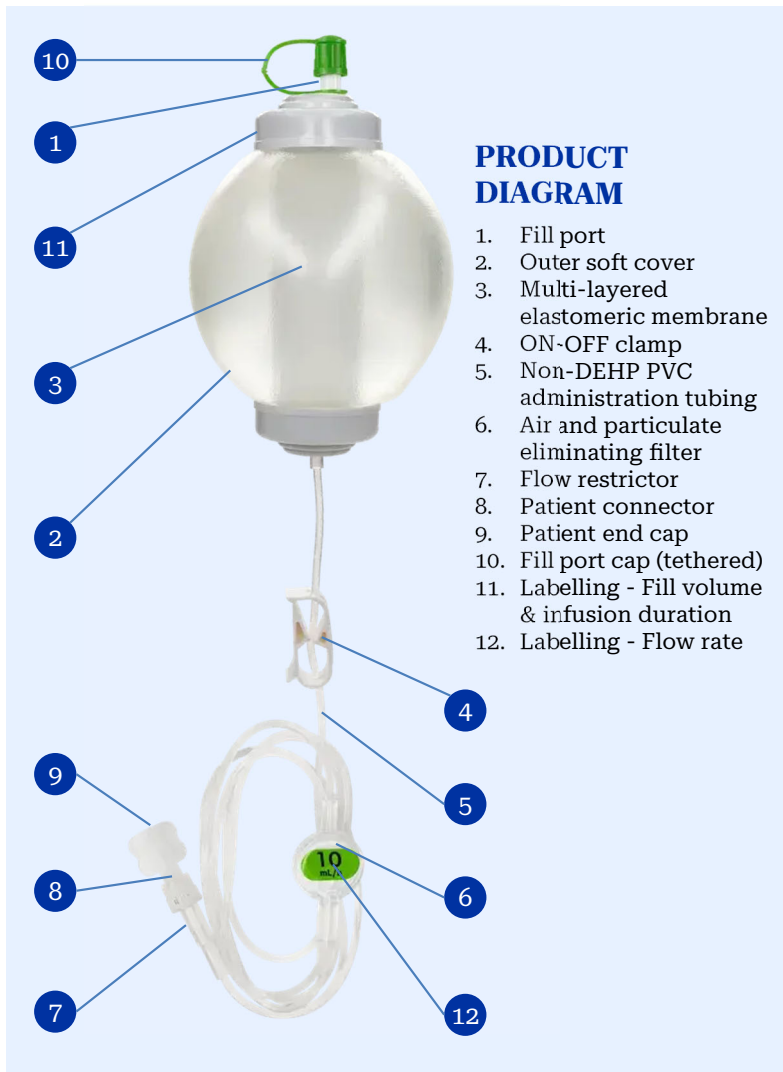




SMARTeZ[®] Pump

Technical Sheet



PRODUCT DIAGRAM

1. Fill port
2. Outer soft cover
3. Multi-layered elastomeric membrane
4. ON-OFF clamp
5. Non-DEHP PVC administration tubing
6. Air and particulate eliminating filter
7. Flow restrictor
8. Patient connector
9. Patient end cap
10. Fill port cap (tethered)
11. Labelling - Fill volume & infusion duration
12. Labelling - Flow rate

INDICATIONS FOR USE STATEMENTS

The SMARTeZ[®] Pump (Long infusion time article) is intended for continuous infusion of medications for general infusion use including pain management. *Routes of administration: intravenous and subcutaneous.*

The SMARTeZ[®] Pump (Short infusion time article) is intended for continuous infusion of medications for general infusion use including antibiotic delivery. *Route of administration: intravenous.*

The SMARTeZ[®] Pump (Chemotherapy article) is intended for continuous infusion of medications for chemotherapy. *Routes of administration: intravenous and intra-arterial.*

MIXING AND USE INFORMATION

- See the drug manufacturer's package insert for drug reconstitution / dilution and storage procedures. Drugs tested for stability and compatibility, representing each route of infusion, include Ceftriaxone, Deferoxamine, Floxuridine, and Vancomycin. Also see drug package insert for drug compatibility with ABS, silicone elastomer, PVC not made from phthalate (DEHP), acrylic, cellulose acetate or e-PFTE and for suitable use with an in-line 1.2 μ m filter.
- Calculate the fill volume by multiplying the desired infusion time (hours) by the nominal flow rate (mL/h) and adding the residual volume. Alteration of dosage is achieved by adjusting the drug concentration – the flow rate is fixed.

INSTRUCTIONS FOR FILLING

-Use Aseptic Technique

1. Unscrew the disposable protective fill port cap with the sterile color-coded fill port cap connected.
2. SMARTeZ[®] Pump can be filled with a syringe or automated filling device. Remove trapped air from the filling device and attach it securely to the fill port.
3. Close the ON-OFF clamp and fill the SMARTeZ[®] Pump with no more than the maximum recommended volume. When using a syringe to fill, push the plunger to dispense the fluid. Do not push the barrel onto the fill port as the syringe tip or fill port may break. Repeat as necessary.
4. Remove filling device from the fill port. Remove disposable protective fill port cap from the sterile color-coded fill port cap. Attach the sterile color-coded fill port cap to the filled SMARTeZ[®] pump fill port.
5. Label with appropriate pharmaceutical and patient information.

PRIMING THE ADMINISTRATION TUBING

-Use Aseptic Technique

1. Open the ON-OFF clamp.
2. Loosen the patient end cap. Medication will start to flow and fill the tubing. When all air is expelled, tighten the patient end cap.
3. Close the ON-OFF clamp.

PRIMING TECHNIQUE FOR DRUG

-for drugs prone to precipitation

1. Fill SMARTeZ[®] Pump with 10 mL of diluent first.
2. Using the above priming method, prime the tubing.
3. Fill the remaining volume with diluent and medication. At completion, the diluent will fill the entire tubing, protecting it from precipitation, while the pump reservoir will contain medication.

STARTING INFUSION

-Use Aseptic Technique

1. Allow SMARTeZ[®] Pump to warm to room temperature before use, especially when infusate has been refrigerated.
2. Infusion should preferably be started 1 hour after filling.
3. Verify that the ON-OFF clamp is close.
4. Clean patient access site as directed by the hospital or healthcare provider. Attach the patient connector to the injection site.
5. Begin infusion by opening the ON-OFF clamp.

OPERATING CONDITIONS AND SAFETY

Actual infusion time may vary due to the following:

- Filling the device less than the nominal volume generally results in slower flow rate
- Filling the device more than the nominal volume generally results in faster flow rate.
- To achieve claimed flow rate accuracy, infusion should be started one (1) hour after filling the device.
- The safety of the device is validated based on infusion time and an additional 8 hour drug/device contact time.
- Temperature affects viscosity. Higher temperature lowers viscosity resulting in shorter delivery times, while lower temperature increases viscosity resulting in longer delivery times.
- The device flow restrictors should be close to or in contact with the skin (31°C / 88°F) and the tubing and pump should be under the patients clothing (25°C/ 77°F). For an increase of every 1 (one) °C, the flow rate may increase by 2.5% and conversely for every 1 (one) °C reduction, flow rate may decrease by 2.5%.
- The nominal flow rates are based on sodium chloride (0.9%, 31°C/ 88°F) as reference. Use of 5% dextrose will result in 10% slower flow rate or correspondingly 10% longer delivery times.
- Avoid getting alcohol or detergents on the filter which may cause leakage from the air eliminating filter.



WARNINGS

- Do not use if packaging or product is damaged or opened. Do not use in infusion regimens by patients who do not possess the mental, physical or emotional capability to self-administer their therapies or who are not under the care of responsible individuals. This warning includes paediatrics as they are not capable of using the devices by themselves.
- Do not immerse the pump in water. Prevent the filter from getting wet.
- Do not use with pressure infusion devices.
- When administering through the intra-arterial and subcutaneous routes where back pressure is expected, flow rate will decrease.
- Do not exert pressure or play with filled device and take caution when used with immobilized patients and to avoid device being slept on. Applied pressure may result in rupture or breakage and will result in increased flow rate. In case of spillage of medication, see drug MSDS for appropriate actions.
- Do not re-sterilize. Strictly for single-use and pump must be discarded in accordance with local regulations.
- Store under general warehouse conditions at 68°F to 77°F (20°C to 25°C). Protect from light sources and heat. Keep dry.
- Drug products should be stored in their approved containers and closures.
- Do not store in freezer.

CONTRAINDICATIONS

- Infusion of insulin, blood or blood products, TPN, lipids or fat emulsions.
- Infusion of any solutions that are not compatible. Consult the pharmaceutical manufacturer's precautions and guidelines to ensure that the medications used will not interact with the device that may possibly cause damage, leakage or precipitation.
- Intra-articular infusion of local anesthesia.
- Infusion of anesthetics in neonates, infants and children below 5 years of age.

SINGLE USE ONLY

SMARTeZ® Pump is designed for optimal performance, effectiveness and safety as a single-use device and not for reuse. Performance, effectiveness and safety may be compromised if the device is reused.

CAUTION : Federal (USA) Law restricts this device to be sold by or on the order of a physician.

INDICATED MAX/MIN VOLUMES

Epic Medical recommends filling at the indicated nominal volume to avoid varying flow rates (See operating conditions and safety)

Nominal Volume	50- 60mL	100 – 125mL	200 – 250mL	270 – 400mL	500mL
Min Fill Volume	40mL	80mL	200mL	240mL	400mL
Max Fill Volume	85mL	150mL	250mL	400mL	500mL

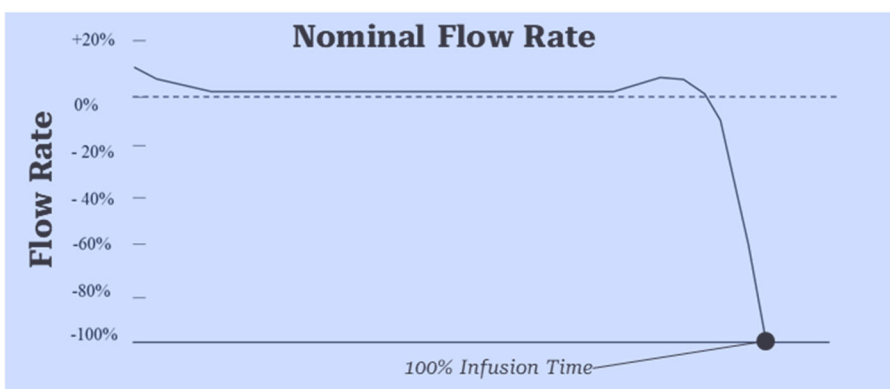
RESIDUAL VOLUMES

Maximum volume remaining after infusion

Nominal Volume	Residual Volume
50 – 125mL	2.0mL
200 – 300mL	3.5mL
400 – 500mL	5.0mL

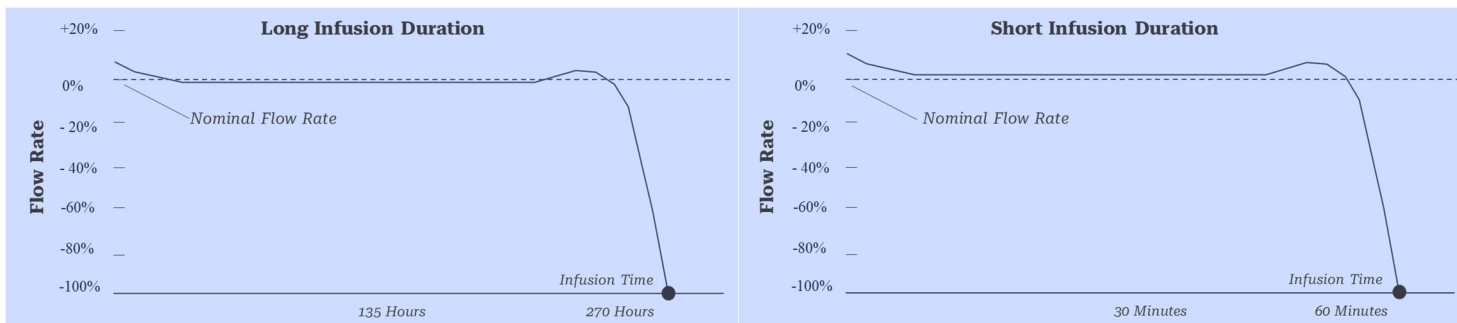
EXPECTED FLOW PROFILE DIAGRAM:

Flow rate profile of a pump filled at nominal volume



NOMINAL FLOW RATE DIAGRAMS:

Flow rate profiles of long infusion time and short infusion time pumps are similar compared to the expected flow profile



OVER & UNDERFILLING DATA (SHORT DURATION INFUSION)

The following tables contain the approximated delivery time at a particular fill volume. Epic Medical recommends all pumps to be filled at their indicated nominal fill volume.

Item Code	481032	481092	481152	481042	481122	481101	481132	481062	481012	481142	481071	481052	481081	481022
Nominal Fill Volume	50mL	100mL	250mL	100mL	250mL	400mL	250mL	250mL	100mL	200mL	400mL	250mL	500mL	250mL
Nominal Flow Rate	50mL/H	50mL/H	50mL/H	100mL/H	100mL/H	100mL/H	125mL/H	175mL/H	200mL/H	200mL/H	200mL/H	250mL/H	250mL/H	500mL/H
Approx. Delivery Time (Hours:Min)	Table Cells Indicate Fill Volume													
0:25									80mL					200mL
0:30									100mL					250mL
0:45	40mL			80mL					150mL			200mL		
1:00	50mL			100mL						200mL		250mL		
1:15	62.5mL			125mL				200mL		250mL	240mL			
1:30	75mL	80mL		150mL				250mL			300mL			
1:35	85mL	85mL									317mL			
1:45		87.5mL					200mL				350mL			
2:00		100mL			200mL		250mL				400mL		500mL	
2:15		112.5mL			225mL									
2:30		125mL			250mL	240mL								
2:45		137.5mL				275mL								
3:00		150mL				300mL								
3:30						325mL								
4:00			200mL			400mL								
4:30			225mL											
5:00			250mL											

OVER & UNDERFILLING DATA (LONG DURATION INFUSION)

Item Code		480051	480011	480181	480081	480610*	480061	480031	480161	480131	480091	480041	480141	480111	480071	481171
Nominal Fill Volume		60mL	60mL	100mL	100mL	100mL	120mL	125mL	270mL	270mL	270mL	270mL	400mL	400mL	400mL	500mL
Nominal Flow Rate		2mL/H	5mL/H	0.5mL/H	2mL/H	5mL/H	4mL/H	5mL/H	2mL/H	4mL/H	5mL/H	10mL/H	4mL/H	5mL/H	10mL/H	20mL/H
Approx.Delivery Time (Hours:Min Days)		Table Cells Indicate Fill Volume														
8			40mL													
10			50mL													
12			60mL													
16			80mL			80mL		80mL								
17			85mL			85mL		85mL								
18						90mL		90mL								
20		40mL				100mL	80mL	100mL								
24	1d	48mL				120mL	96mL	120mL				240mL			240mL	
25	1d	50mL				125mL	100mL	125mL				250mL			250mL	500mL
27	1d	54mL				135mL	108mL	135mL				270mL			270mL	
30	1d	60mL				150mL	120mL	150mL				300mL			300mL	
36	1.5d	72mL					144mL					360mL			360mL	
37:30	1.5d	75mL					150mL					375mL			375mL	
40	1.5d	80mL			80mL							400mL			400mL	
46	1.6d				92mL											
48	2d				96mL						240mL			240mL		
50	2d				100mL						250mL			250mL		
54	2d				108mL						270mL			270mL		
60	2.5d				120mL					240mL	300mL		240mL	300mL		
67:30	2.5d				135mL					270mL	337.5mL		270mL	337.5mL		
72	3d				144mL					288mL	360mL		288mL	360mL		
75	3d				150mL					300mL	375mL		300mL	375mL		
80	3d									320mL	400mL		320mL	400mL		
100	4d									400mL			400mL			
120	5d								240mL							
125	5d								250mL							
135	6d								270mL							
144	6d								288mL							
150	6d								300mL							
160	6.5d			80mL					320mL							
168	7d			84mL					336mL							
200	8.5d			100mL					400mL							
300	12.5d			150mL												

*Not available in the USA



OVER & UNDERFILLING DATA (CHEMOTHERAPY INFUSION)

Item Code		484011	484031	484021	484041	484051	-*
Nominal Fill Volume		100mL	120mL	270mL	270mL	270mL	300mL
Nominal Flow Rate		2mL/H	4mL/H	2mL/H	5mL/H	10mL/H	6mL/H
Approx.Delivery Time (Hours:Min Days)		Table Cells Indicate Fill Volume					
20			80mL				
24	1d		96mL			240mL	
25	1d		100mL			250mL	
27	1d		108mL			270mL	
30	1d		120mL			300mL	
36	1.5d		144mL			360mL	
37:30	1.5d		150mL			375mL	
40	1.5d	80mL				400mL	240mL
46	1.6d	92mL					276mL
48	2d	96mL			240mL		288mL
50	2d	100mL			250mL		300mL
54	2d	108mL			270mL		324mL
60	2.5d	120mL			300mL		360mL
62	2.5d	124mL			310mL		372mL
67	2.5d	134mL			335mL		400mL
72	3d	144mL			360mL		
75	3d	150mL			375mL		
80	3d				400mL		
120	5d			240mL			
125	5d			250mL			
135	6d			270mL			
144	6d			288mL			
150	6d			300mL			
168	7d			336mL			
200	8.5d			400mL			

*Not available in the USA

